The effectiveness of rocker sole shoes in chronic low back pain

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Abstract

Shoes with a rocker sole are marketed as reducing low back pain. There is minimal evidence to support these claims. This investigation compared rocker sole shoes to flat sole shoes in people with chronic low back pain (CLBP).

The thesis reports findings of a randomised clinical trial and a series of biomechanical experiments. Following preparatory pilot and reliability studies, 115 people with CLBP were randomised to wear rocker sole shoes or flat sole shoes; all participants attended an exercise and education programme. Participants were assessed without knowledge of group allocation pre-randomisation, at six weeks, six months, and one year (main outcome point). Primary outcome was the Roland Morris Disability Questionnaire (RMDQ). Analysis was by intention-to-treat.

Biomechanical experiments recruited 20 participants from the main study and investigated effects of wearing rocker sole and flat sole shoes on standing balance and gait, immediately and after 6 months of shoe wear, using centre of pressure and motion-analysis derived kinetic, kinematic and spatio-temporal measures. Balance and gait in people with and age- and gender-matched controls without CLBP were compared.

Rocker sole shoes were no more beneficial than flat sole shoes for CLBP patients; flat sole shoes were more beneficial in a sub-group of CLBP aggravated by standing or walking. Biomechanical studies found rocker sole shoes introduced immediately greater postural instability than flat sole shoes but neither shoe had long-term training effects on postural control. Furthermore, although both shoes resulted in small immediate changes in kinetic, kinematic and spatio-temporal parameters of shod gait, neither shoe had long-term training effects on these parameters in barefoot gait. Finally, in contrast to some previous research, postural control during standing, and kinetics, kinematic, and spatio-temporal parameters during gait were similar between people with and without CLBP. The implications of these findings are discussed.

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Abbreviations

APOS	‘All Phases of Step Cycle’ (footwear device manufacturer)
ASICS	‘Anima sana in corpore sano’ (Latin phrase meaning ‘a sound mind in a sound body’) (sports trainer manufacturer)
CoP	Centre of pressure
$CoP_{RMSE\ AP}$	Root mean squared error of the centre of pressure in the antero-posterior direction
$CoP_{VEL\ AP}$	Velocity of the centre of pressure in the antero-posterior direction
CI	Confidence interval
C.I.	Chief investigator
CLBP	Chronic low back pain
EQ-5D-3L	EuroQol – five dimensions – three levels
GRF	Ground reaction force
HADS	Hospital Anxiety and Depression Score
ICC	Intraclass correlation coefficient
L1	1^{st} lumbar vertebrae
LBP	Low back pain
MBT	Masai Barefoot Technology
NICE	National Institute for Health and Clinical Excellence
NRS	Numerical Rating Scale
ODQ	Oswestry Disability Questionnaire
P.I.	Primary investigator
PSFS	Patient Specific Functional Score
RCT	Randomised controlled trial
REC	Research ethics committee
RMDQ	Roland Morris Disability Questionnaire
SD	Standard deviation

SEM	Standard error of measurements
SLR	Straight leg raise
SPSS	Statistical package for the Social Sciences
T1	1st Thoracic vertebrae
T2	2^{nd} Thoracic vertebrae
T12	12^{th} Thoracic vertebrae
TSK	Tampa Scale of Kinesiophobia

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1 Introduction: Chronic Low Back Pain

1.1 Aim of chapter

This chapter defines chronic low back pain (CLBP), reports its incidence, prevalence and cost to society. The effectiveness of exercise therapy, a recommended conservative treatment in the management of chronic low back pain is discussed, and potential mechanisms underpinning CLBP are presented.

1.2 Definition of chronic low back pain

Defining CLBP is complex, with little agreement between studies regarding area of symptoms, expression of pain, and duration of symptoms (Stanton et al., 2010). Without an agreed definition, it is difficult to interpret and compare results of randomised, controlled trials (RCTs) that investigate CLBP.

The National Institute for Health and Clinical Excellence (NICE) define non-specific LBP as "tension, soreness and/or stiffness in the lower back region for which it isn't possible to identify a specific cause of the pain" (NICE, 2009). 'Specific causes' for the pain include: fracture, malignancy, infection, ankylosing spondylitis and other inflammatory disorders (NICE, 2009). The guideline defines the lower back as the area bound by the bottom of the 12th rib and the buttock creases; when pain is also felt in the upper legs the back pain is usually the more dominant (NICE, 2009). The NICE guideline definition of non-specific LBP will be used for the purpose of participant recruitment in this thesis (NICE, 2009). 'Chronic' will mean a duration of pain for three months or longer (International Association for the Study of Pain, 1986). Patients presenting with radicular pain supposed by the clinician to result from nerve root irritation will not participate in the studies described in this thesis.

1.3 Epidemiology and financial impact of chronic low back pain

Low back pain (LBP) is reported by 49% to 80% of the general population at some stage during their lives (Airaksinen et al., 2006; Koes et al., 2006). In 2008, the incidence of chronic back problems was 31 per 1000 in males and 28 per 1000 in females (Office for National Statistics, 2008). Annually, 7% of the adult population will present to their general practitioner with LBP (McCormick et al., 1995) accounting for 14% of all musculoskeletal consultations (Jordan et al., 2010). Five to twenty percent will develop CLBP (Johanssen et al., 1995; Klaber Moffett et al., 1986; Quittan, 2002; Tortensen et al., 1998). If low back pain progresses to a chronic status it is likely to run a recurrent course in the majority of patients (Carey et al., 1999; Korff, 1994). The financial implications of LBP are substantial; in 1998 the direct healthcare costs of LBP in the UK were estimated at £1623 million (Maniadakis and Gray, 2000).

1.4 Possible biomechanical mechanisms underpinning chronic low back pain

Although a wealth of research on CLBP exists, the causative mechanisms underpinning CLBP remain equivocal. To understand CLBP and propose appropriate treatment it is important to recognise the many different mechanisms thought to underpin the condition. Further understanding of potential mechanisms may assist researchers in developing improved treatment approaches, more specifically directed at influencing such mechanisms. When considering the musculoskeletal system, it has been suggested that postural control deficits (Byl and Sinnott, 1991; Della Volpe et al., 2006; Henry et al., 2006; Luoto et al., 1996; Mientjes and Frank, 1999; Takala et al., 1997a) and biomechanical adaptations during gait (Keefe and Hill, 1985; Khodadadeh and Eisenstein, 1993; Vogt et al., 2001) are contributing factors to the presence and recurrent nature of CLBP.

1.4.1 Postural stability and control strategies in chronic low back pain

Postural control strategies provide postural stability to the human body during movement and the maintenance of static postures (Horak and Nashner, 1986). Small perturbations during standing result in sway at the ankle joint in order to maintain the body's centre of mass within its base of support; this is called the ankle strategy (Horak and Nashner, 1986). Although an ankle strategy is adequate to maintain upright stance on a flat surface, it is not adequate when on a short base or during more challenged standing conditions (Horak and Nashner, 1986). During large perturbations greater movements at the hip assist in the maintenance of the body's centre of mass within its base of support; this is known as the hip strategy (Horak and Nashner, 1986). A third strategy called the stepping strategy is implemented when a perturbation displaces the centre of mass outside an individual's base of support. Individuals with CLBP have demonstrated altered postural control strategies when compared to asymptomatic individuals (Byl and Sinnott, 1991; Della Volpe et al., 2006; Henry et al., 2006; Luoto et al., 1996; Mientjes and Frank, 1999; Takala et al., 1997a).

Della Volpe et al. (2006) investigated whether CLBP patients with mild disability exhibited altered postural control during quiet standing when compared with asymptomatic, age-matched controls. Six standing conditions, varying visual and proprioceptive input, were assessed. Measures of postural stability (centre of pressure (CoP) velocity and displacement) were recorded from a force plate. The CLBP patients oscillated with a greater velocity than asymptomatic patients during the more challenging balance conditions, indicating reduced postural stability in the CLBP group (Ruhe et al., 2011a). However, the sample size was small, and anthropometric data capable of influencing CoP excursions, such as age (Choy et al., 2003; Era and Heikkinen, 1985; Hasselkus and Shambes, 1975; Hue et al., 2007), height (Chiari et al., 2002; Hue et al., 2007), and weight (Chiari et al., 2002; Hue et al., 2007) were omitted for the control group, hence these findings must be regarded with caution.

Brumagne et al. (2008) investigated the influence of support surface on postural stability and control strategies in those with and without CLBP. Twenty one participants with CLBP (fourteen women, seven men) and twenty four asymptomatic individuals were assessed. There were no differences in postural stability between groups during normal standing on a firm support surface with eyes open, however, when standing during more challenging standing conditions (visual occlusion or the addition of ballistic arm movements) the CLBP group demonstrated significantly larger CoP displacements compared to the pain-free controls. Due to the larger CoP displacements in the CLBP group it was concluded that people with CLBP favour an ankle strategy during unstable standing conditions when a hip strategy is thought to be more biomechanically effective (Horak and Nashner, 1986). This abnormal postural strategy in people with CLBP may result from a reduced ability to initiate a hip strategy secondary to co-contraction of superficial muscles around the hip (Mok et al., 2004).

Mok et al. (2004) observed standing balance in twenty four participants with CLBP and twenty four age- and gender- matched controls. Participants stood on either a flat surface or a short base (a block 9cm in length), on one or both legs, whilst visual inputs were varied. Horizontal shear force, CoP excursion, and the number of successful balance trials were assessed. CLBP participants were found to have poorer balance when compared to the asymptomatic group. A reduced 'hip strategy' (inferred from a reduction in antero-posterior horizontal shear force) was demonstrated in participants with CLBP during standing trials on firm ground. These findings suggest that people with CLBP have poorer balance and altered postural control strategies in standing when compared to asymptomatic individuals.

It is likely that a number of different mechanisms contribute to the presence of these altered postural control strategies. Firstly, during quiet standing the mean CoP position is more posterior in people with back pain (Byl and Sinnott, 1991; Mientjes and Frank, 1999). Such posterior deviations of the CoP may influence the activation of ankle and hip strategies during standing due to a biomechanical ease or advantage for the recruitment of certain muscle groups to maintain the centre of mass within the base of support. Although the resting position of the CoP may help to explain why a different postural strategy may be used, it remains unclear as the why, in people with CLBP, the CoP should rest more posterior than it would in asymptomatic people.

Reduced activity of the deep abdominal (Hodges and Richardson, 1996; Hodges and Richardson, 1998; Hodges and Richardson, 1999) and paraspinal muscles (Ahern et al., 1988; Hides et al., 1996; Ng et al., 2002) have been identified in those with LBP, accompanied by co-contraction of the superficial muscles in the lumbo-pelvic region (Hodges and Moseley, 2003). It has been hypothesised that this superficial muscle co-contraction restricts both range and pace of trunk and hip motion in response to large postural perturbations (Mok et al., 2004). This may result in a stiffened postural appearance, and a possible restriction in the initiation or efficiency of the hip strategy in people with CLBP. This theory may also account for the increased, and supposed compensatory, ankle strategy observed during more challenging standing conditions (Brumagne et al., 2008; Mok et al., 2004).

Proprioception is the ability to determine exactly where a body part is in space (Sherrington, 1907). Reduced lumbar spine proprioception (Brumagne et al., 2000; Gill and Callaghan, 1998; Parkhurst and Burnett, 1994; Taimela et al., 1999) has been reported in patients with LBP when compared to asymptomatic individuals. These deficits, hypothesized to cause delayed muscle responses to sudden trunk loading (Hodges and Richardson, 1996; Hodges and Richardson, 1998; Radebold et al., 2000; Wilder et al., 1996), may reduce preparatory spinal movement (Mok et al., 2007), adversely affecting spinal control, and increasing spinal displacement (Mok et al., 2007). Hence, reduced proprioception has been proposed as a causative factor underpinning the presence of CLBP (Brumagne et al., 2000). However, uncertainties exist around the mechanisms underpinning the origin of such proprioceptive deficit. A poorer ability to accurately reposition the lumbar spine in people with low back pain compared to people without has been observed (Brumagne et al., 2000; Gill and Callaghan, 1998; Taimela et al., 1999), suggesting that the presence of pain may contribute to the proprioceptive deficit. The presence of pain stimuli may cause a reduction of position sense (Rossi et al., 1998) by altering neuronal excitability through increased presynaptic inhibition of muscle afferents at a spinal level (Rossi et al., 1999) or the down regulation of cortical systems involved in proprioceptive processing (Porro et al., 2002; Rossi et al., 2003). Alternatively, injury to the lumbar spine, resulting in the presence of dysfunctional mechanoreceptors in surrounding muscles and ligaments (the main stabilizers of the lumbar spine) (Hodges and Richardson, 1998; Parkhurst and Burnett, 1994; Radebold et al., 2000; Taimela et al., 1999) offers a further mechanism which may explain the altered postural control observed in those with CLBP.

The exact mechanisms underpinning altered postural stability and control strategies in people with CLBP are unclear (Cholewicki et al., 2003). Furthermore, it is not known whether differences in postural control mechanisms in people with CLBP are protective or maladaptive responses, or are epiphenomena (secondary symptoms occurring alongside a disease or condition but not directly related to its cause (Stedman, 2005)) of a different mechanism underpinning CLBP. If altered postural strategies are detrimental to recovery, treatment directed at influencing these strategies may result in more beneficial outcomes for people with CLBP. This is discussed in *2.4 (p25)*. However, it is unclear whether approaches to 'normalise' these postural control alterations may be possible or effective.

1.4.2 Gait, heel strike transients and shock attenuation alterations in chronic low back pain

Alterations in gait have been observed in people with CLBP when compared to asymptomatic individuals. Whilst walking, people with LBP increase activity in lumbar extensors muscles (Arendt-Nielsen et al., 1996), reduce walking speed and step length, and increase their cadence (steps per minute) when compared to age-matched asymptomatic individuals (Keefe and Hill, 1985; Khodadadeh and Eisenstein, 1993; Vogt et al., 2001). These gait differences in people with LBP may be an attempt to modify external and internal forces imposed on the body by limiting hip and spine ranges of motion (Lee et al., 2007). Reduced pain and improved functional ability have been reported in people with CLBP when the loading force on heel strike was reduced from walking with viscoelastic shoe insoles (Folman et al., 2004; Wosk and Voloshin, 1985). The reduced gait speed in people with CLBP may, therefore, be an attempt to attenuate vertical ground reaction forces (GRF) – the positive linear correlation between gait velocity and vertical GRF in pain free individuals (Keller et al., 1996) reinforces this theory. Alternatively, people with LBP may inadvertently adopt a 'protective guarding' gait pattern, modifying their pattern of muscular activity and restricting movements of the spine (Ahern et al., 1988) in an attempt to reduce the sensation of pain. Similarly, the 'fear avoidance' model (Leeuw et al., 2007) has been implicated as a possible cause of the altered gait. Psychological factors associated with low back pain, such as anxiety, hypervigilance and catastrophising, may lead to the avoidance or adaptation of physical activities, such as fast walking, due to the fear of an increase in pain (Al-Obaidi et al., 2003).

However, consequences of such gait alterations may contribute to the development and chronicity of symptoms. A reduction in step length and walking speed decreases counter-rotation between the lumbar, thoracic and pelvic regions during gait. This produces longer periods of loading on the lumbar spine during gait (Callaghan et al., 1999), which may be detrimental to spinal structures in the long term; whereas more cyclic, shorter periods of loading, thought to be less detrimental, occur during faster walking (Callaghan et al., 1999). Although gait alterations may initially be protective, such alterations may have detrimental long term consequences to those already in pain.

Heel strike force transients during gait have been implicated as a potential cause and aggravator of LBP (Light et al., 1980; Voloshin and Wosk, 1982). Heel-strike, the first component of the stance phase of the gait cycle, introduces a shock wave that is propagated upwards through the skeleton as a transient force (Light et al., 1980). The calcaneal heel pad, cartilage of the joints and their subchondral cancellous bone are thought to attenuate these transients. Although transient forces have been proposed as harmful to the musculoskeletal system, much of the evidence for this theory comes indirectly from animal studies (Radin et al., 1978; Radin et al., 1982; Radin et al., 1973; Simon et al., 1972). Although greater heel strike magnitudes have been observed in people with early signs of knee osteoarthritis when compared with age-matched asymptomatic individuals (Radin et al., 1991), little direct evidence indicating these transient forces are harmful under physiological conditions in humans exists; degenerative changes occur over long periods of time, making it difficult to perform adequate prospective studies. Voloshin and Wosk (1982) investigated the ability of the musculoskeletal system to attenuate shock during gait in asymptomatic participants, participants with LBP, and participants with other degenerative joint diseases. Accelerometers were attached to each participant's forehead and femoral condyle. Levels of shock attenuation in non-LBP subjects were higher than in the LBP group. It was concluded from these findings that the presence of LBP correlated with a reduced shock absorbing capacity of the human musculoskeletal system from the femoral condyle to the forehead. More valid results may have been obtained by attaching accelerometers to points closer to the lumbar spine; alternatively, more accurate measurements may have been derived by using bone mounted accelerometers. Although research with bone mounted accelerometers has been conducted (Mendelson et al., 1998) this invasive approach has medical and ethical considerations. Due to the paucity of longitudinal data it is not known whether observations of reduced shock attenuation (Voloshin and Wosk, 1982) and increased heel strike transients (Radin et al., 1991) existed pre- or post-onset of a participant's pain, but provide a further potential mechanism to explain its presence.

The manner in which a person stands or mobilises may contribute to the presence of CLBP. Closer analysis of the neuro-musculoskeletal systems involvement in the control of each of these activities, may lead to a greater understanding of the mechanisms underpinning CLBP.

1.5 Conservative management of chronic low back pain

As a result of the non-specific nature of the majority of CLBP, numerous conservative treatments have been proposed (Hayden et al., 2005a). National (NICE, 2009) and international guidelines (Koes et al., 2001) recommend exercise as a key component in the management of CLBP and will be discussed further within this thesis. Invasive procedures (such as acupuncture and surgery) and other approaches (such as manual therapy and psychology) recommended in the management of CLBP (NICE, 2009) fall outside the scope of this research, hence, will not be discussed further within this thesis.

1.5.1 Exercise and chronic low back pain

The NICE guideline for CLBP summarised findings into the effectiveness of general exercise programmes compared to 'usual care' on pain, and functional disability (NICE, 2009). The guideline (NICE, 2009) recommends that people with CLBP be advised to keep physically active. In agreement with other systematic reviews (Hayden et al., 2012; Koes et al., 2006; Koes et al., 2001), attendance to a structured, supervised, exercise programme, including aerobic activity, muscle strengthening, stretching, or tasks to challenge postural control is recommended for people with CLBP (NICE, 2009). The NICE guideline recommendations regarding exercise therapy are drawn from only 12 studies, all relating to participants with a CLBP history of between six weeks and one year. It is unclear whether response to treatment for people with CLBP of a duration greater than one year may differ to that of individuals with less chronic presentations, hence caution must be taken when relating these findings to a more chronic population.

Although, previous research demonstrates strong evidence for exercise therapy (Hayden et al., 2012; Koes et al., 2006; Koes et al., 2001; NICE, 2009) no one form of exercise appears to be substantially superior to another (Bogduk, 2004; Unsgaard-Tondel et al., 2010; van Tulder et al., 2006). A systematic review investigating motor control exercises (including motor control, specific spinal stabilisation or core stability exercises) for CLBP (Macedo et al., 2009) concluded, from fourteen randomised, controlled trials (RCTs), that motor control exercises offer no more benefit than manual therapy, surgery or other forms of exercise. Furthermore, although a recommended 'best practice' (NICE, 2009), exercise intervention effects are small with minimal improvements in disability and pain at long term follow-up in people with CLBP (Keller et al., 2007).Therefore, it is important to continue investigating, with high quality RCTs, novel and evidence based treatment approaches for those with CLBP.

1.5.2 Footwear as a treatment for chronic low back pain

Interventions yet to be investigated in robust RCTs may offer additional benefits, for people with CLBP, to the minimal improvements reported following ‘best practice’ interventions. Altered biomechanics during standing and gait in people with CLBP have been suggested as underpinning mechanisms contributing to the presence and recurrence of symptoms (Brumagne et al., 2008; Mok et al., 2004). Footwear has demonstrated an ability to influence human biomechanics, such as balance (Nigg et al., 2006b), spatio-temporal parameters of gait (Demura et al., 2012; Keenan et al., 2011; Lythgo et al., 2009), and joint kinematics (Taniguchi et al., 2012), hence, footwear may offer benefit to people with CLBP.

Over the past 15 years shoe companies have designed, footwear marketed with strong advertising claims of the shoes ability to influence low back pain (Masai Barefoot Technology GB Ltd, 2011). Companies include Masai Barefoot Technology (MBT) GB Limited™, Chung Shi ™, Fitflops ™, Reebok’s ‘Easy Tone’ ™, and Skechers ‘Shape up’ ™. Currently there is minimal evidence supporting or rejecting these claims. Hence, there is a need for large high quality RCTs, investigating potential effects of footwear on LBP, to determine whether footwear type can complement the current best practice approaches for CLBP. This is discussed in detail in *Chapter 2 (p22).*

1.6 Conclusions

The mechanisms underpinning CLBP remain unclear. In order to establish effective treatment approaches for those with CLBP a sound knowledge of the mechanisms underpinning the presence of pain is necessary. This lack of knowledge may contribute to the minimal clinical benefits observed in those with CLBP even when receiving current best practice treatment approaches. It is feasible that a novel approach to CLBP management, a rocker sole shoe, marketed with a shock absorbing heel and an unstable sole, promoting instability during standing and walking, may positively influence biomechanical mechanisms proposed to underpin CLBP. The following chapter will discuss how footwear may positively influence CLBP.

2 The potential for footwear to influence chronic low back pain

2.1 Aim of chapter

This chapter summarises previous research investigating the effect of footwear on the musculoskeletal system, and suggests how rocker sole shoes may positively influence chronic low back pain (CLBP) by affecting the underpinning mechanisms presented in *Chapter 1 (p15).*

2.2 Evolution of footwear

In 1938, an American anthropologist discovered what is thought to be the oldest surviving footwear in a cave in North America (Kuttruff et al., 1998). The sandals are thought to be 9,300 to 10,500 years old. However, the first suggestion of the existance of footwear appeared in Spanish cave paintings, from the late Paleolithic period (15,000 years ago), showing humans wearing animal skins around their feet.

The observation of anatomical changes in the structure of human foot bones, between 10,000 and 100,000 years ago (Trinkaus and Shang, 2008), has lead researchers to propose that the use of shoes began at a much earlier time point. A reduction in thickness, size and strength of the proximal phalanges was observed in toe bones disovered in a cave in China dating from 26,000 to 40,000 years ago. It was hypothesised that wearing shoes reduced the forces on these toes during walking, resulting in shorter and thinner toes (Trinkaus and Shang, 2008). These findings suggest that footwear may have the potential to change human biomechanics.

2.3 Footwear and the modern human musculoskeletal system

Footwear continues to evolve. Shoes are specifically designed to benefit participation in daily and sporting activities. Different designs of footwear have demonstrated differing influences on human biomechanics (Demura et al., 2012; Elbaz et al., 2009; New and Pearce, 2007; Nigg et al., 2006b; Romkes et al., 2006; Taniguchi et al., 2012). Over the past decade footwear manufacturers have made claims that, through altering human biomechanics, their footwear may benefit a variety of musculoskeletal conditions, for example, knee pain and low back pain (Masai Barefoot Technology GB Ltd, 2011). A recent example are shoes manufactured with convex soles, commonly known as rocker sole shoes. If the claims made by shoe manufacturers are substantiated, selection of appropriate footwear may add benefit to the management of certain musculoskeletal conditions. For symptomatic individuals, such as those with CLBP, there is a paucity of evidence in peer-reviewed literature to supporting these claims. Therefore, this thesis will investigate whether a rocker sole shoe may positively influence the musculoskeletal dysfunctions or adaptations observed in people suffering from CLBP.

2.4 Rehabilitation of postural control in chronic low back pain

Poorer postural stability and altered postural strategies have been identified in people with CLBP compared to asymptomatic individuals, as described in *1.4.1 (p17).* Alterations to postural stability and postural strategy in the acute stages of LBP may be an attempt to reduce musculoskeletal discomfort (Lafond et al., 2009). However, if maintained following the acute stage of injury, these changes may mean the dynamic stability of the lumbar spine is compromised, potentially increasing a person's vulnerability to further injury, or exacerbating an existing back problem (Radebold et al., 2001). Rehabilitation exercises aimed at training postural control to address this altered system therefore seems a plausible treatment approach.

Rehabilitation with proprioceptive or balance training has been shown to be a successful treatment in other regions of the body (Fitzgerald et al., 2000; Tropp and Askling, 1988). In people with functional ankle instability, ten minutes of proprioceptive exercise on a wobble board, five times a week for 10 weeks, resulted in increased ankle evertor muscle strength, improved postural stability, and a reduced sensation of the ankle giving way when compared to people not undergoing wobble board training (Tropp and Askling, 1988). Similarly, in anterior cruciate ligament (ACL) deficient knees, specific perturbation rehabilitation programmes (using a roller board and wobble board for two to three sessions a week for approximately five weeks) resulted in a reduced incidence of giving way of the knee during athletic activity at six months compared to those receiving standard ACL rehabilitation (Fitzgerald et al., 2000).

The potential impact of rehabilitation techniques aimed at improving postural control in people with CLBP is unclear. Comparison of the effectiveness of co-ordination training (emphasising stability and balance exercises) with muscle endurance training (focusing on low back, abdominal, shoulder, hip and knee muscles) in people with CLBP has been conducted (Johanssen et al., 1995). Participants in both groups attended a one hour exercise class, twice a week, over a three month period. Results suggested that proprioceptive and endurance exercises produce similar pain reduction and functional improvement at three and six months. However, researchers were not blind to participant group allocation, and it is unclear whether the pain and disability measures assessed were valid or reliable.

A manufacturer of rocker sole shoes (Masai Barefoot Technology GB Limited, London, UK) have suggested that the unstable sole in their footwear can help to increase muscle activity and improve balance, hence, can be used as a ‘sensorimotor training device’, easily incorporated into everyday life that will benefit functional daily activities (Masai Barefoot Technology GB Ltd, 2011). Nigg et al. (2006b) demonstrated the unstable nature of the rocker sole during standing. In a small asymptomatic sample (n=8) greater centre of pressure (CoP) excursions (indicating poorer postural stability) in both antero-posterior (AP) and medio-lateral (ML) directions were recorded in rocker sole compared to flat sole shoes. The unstable surface of the rocker sole shoes appears to challenge postural stability in a similar way to a wobble board.

Wearing rocker sole shoes and hence ‘training’ for hours each day may enhance the effectiveness of training balance when compared to other interventions, such as the wobble board, offered at decreased frequencies and durations (Fitzgerald et al., 2000; Tropp and Askling, 1988). If rocker sole shoes serve as an effective training device for joint stability and proprioception training they may provide clinical benefit to those with CLBP who present with impaired postural control.

2.5 Influencing spatio-temporal parameters of gait with footwear in chronic low back pain

Individuals with LBP walk slower, and take shorter steps with a greater cadence when compared with age-matched asymptomatic individuals (Keefe and Hill, 1985; Khodadadeh and Eisenstein, 1993; Vogt et al., 2001). These gait alterations may contribute to the chronicity of LBP symptoms. However, fast walking is thought to offer more benefits to the spine than slow walking (Nutter, 1988). A greater arm swing usually occurs whilst walking faster and this has been found to result in lower lumbar spine moments, muscle activity, and hence a reduction in joint loading (Callaghan et al., 1999; McGill, 2007). Furthermore, Kubo and colleagues (2006) reported higher torso stiffness, a positive co-factor in prevention of and more successful recovery from low back troubles (Nutter, 1988), with faster walking, and Holm and Nachemnson (1983) demonstrated that lumbar motion during faster walking increased nutrition to the intervertebral disc suggesting faster walking to be a more advantageous to the spine than slow walking. These findings complement the suggestion by Elbaz et al. (2009) that the increased walking speed observed following the use of specialised footwear may positively influence the symptoms of LBP.

Elbaz et al. (2009) investigated the effects of a 'novel biomedical device' - the APOS (All Phases of Step cycle) system - on gait in nineteen CLBP patients. The footwear device comprises of two semi-circular discs which attach to the base of a shoe. At baseline, participants' spatio-temporal parameters were assessed during barefoot gait at self-selected speed. After twelve weeks of wearing the APOS system, velocity, cadence, and step length increased. No pain or functional outcome measures were recorded, hence, it is unknown whether biomechanical changes correlated with clinical improvement; nor was participant familiarity with the testing procedure considered as a possible contributing factor to the differences observed at follow-up. Furthermore, participant compliance with wearing the footwear device is unclear. However, their study suggests that footwear has the potential to influence barefoot gait in CLBP.

If other types of footwear such as the rocker sole MBT shoe can influence gait parameters such as walking speed, in a similar manner to that demonstrated from use of the APOS system, a positive influence on low back pain may occur. Recommendations by a rocker sole shoe manufacture suggest walking at a quicker pace than normal, with a slightly shorter step length, whilst gently swinging the arms *(5.3.6, p68).* All three of these suggested gait instructions have been associated with decreased load on the lumbar spine by either increasing lumbar movement during gait (Callaghan et al., 1999) or reducing the transient forces initiated at heel-strike (Folman et al., 2004; Wosk and Voloshin, 1985) from reaching the spine.

In contrast to these walking recommendations and the findings of Elbaz et al. (2009), walking in rocker sole shoes (MBT shoes) compared to normal footwear has demonstrated decreases in cadence, stride length, step length and walking speed (Romkes et al., 2006). However, methodological differences between the studies may explain the contrasting findings; in the APOS study participants were assessed in barefoot pre- and post- a 12 week intervention period. In the rocker sole shoe study, participants were assessed shod in their normal shoes and in rocker sole shoes. Although a faster gait velocity has been suggested by some to have benefits for those with LBP (Callaghan et al., 1999; McGill, 2007; Nutter, 1988), a slower gait velocity, with concomitant reductions in ground reaction forces (Keller et al., 1996) *(2.6, p28)* may also be beneficial to people with CLBP.

2.6 Influencing shock attenuation and ground reaction forces with footwear in chronic low back pain

As discussed in *1.4.2 (p20),* mechanical stress such as the ground reaction forces during heel strike have been acknowledged as aggravating factors in the aetiology of CLBP. Whittle et al. (1999) stated that the body has two natural defences against potential damage from the heel strike transient (the sharp increase in ground reaction force detected immediately after heel strike): appropriate joint alignment (such as knee flexion) at heel strike and the presence of viscoelastic materials in the heel pad and joints. People with LBP have reported reduced pain and improved functional ability when repetitive axial loading forces during walking were reduced by walking with viscoelastic shoe insoles (Wosk and Voloshin, 1985). Spinal loading can be influenced by footwear type – it has been demonstrated that running in sports trainers compared to barefoot decreases the rate of shock transmission to the spine (Ogon et al., 2001); whereas, increasing footwear heel height increases the loading on the erector spinae muscles when walking (Lee et al., 2001, Mika et al., 2012). A cushioning effect from footwear may assist in reducing external forces reaching the spine, or may influence lower quadrant joint angles during the stance phase of the gait cycle, increasing shock attenuation.

MBT GB Ltd suggest that musculoskeletal disorders such as back pain may be associated with walking on hard flat surfaces, and that walking in MBT shoes will provide a more comfortable heel strike compared to normal shoes due to the 'Masai sensor'- a polyurethane cushion incorporated into the heel portion of the sole (Masai Barefoot Technology GB Ltd, 2011). MBT GB Ltd claim that mobilising in MBT shoes, whereby the curved sole provides a more gentle rolling movement through each step than a flat sole shoe, simulates walking on soft natural terrain such as on sand, hence may reduce supposedly detrimental impact to the musculoskeletal system during gait (Masai Barefoot Technology GB Ltd, 2011).

An unpublished study investigating the effect of shoe type on ground reaction forces in twenty two asymptomatic individuals (Vernon et al., 2004) demonstrated a reduced incidence of transient force peaks when walking in rocker sole shoes compared with normal flat sole shoes. If these findings are replicated in a CLBP population, and if transient heel strike forces are a contributing factor to the presence of LBP, footwear may offer symptom relief to this population.

New and Pearce (2007) reported a small increase in knee flexion angle at heel strike for participants walking in rocker sole shoes compared to their normal footwear. Similarly, during gait, Romkes et al. (2006) reported a greater knee flexion on initial heel strike when in MBT shoes. If this increase in knee flexion improves shock absorption (Whittle, 1999) in the distal musculoskeletal system, potentially reducing the passage of transient forces to the lumbar region, and if recurrent force transients during gait are a contributing factor to the presence of LBP, such biomechanical alterations may influence the symptoms of LBP. However, it is not known whether forces reaching the spine are reduced when wearing a rocker sole shoe compared to when mobilising in a flat sole shoe or whether forces reaching the spine are of a sufficient level to contribute to the pathology of LBP.

2.7 Conclusions

Biomechanical mechanisms have been proposed to underpin CLBP. Wearing footwear influences the biomechanics of the musculoskeletal system. Footwear manufacturers claim that biomechanical effects from wearing their footwear may positively influence musculoskeletal conditions, such as CLBP. Currently there is minimal evidence to support or reject these claims. Hence, there is a need for large high quality RCTs, investigating potential effects of footwear on LBP, to determine whether footwear type can complement the current best practice approaches for CLBP.

3 Evolution of the thesis

Dr Jeremy Lewis (JL) conceived the pilot study protocol and approached Masai GB Limited (the manufacturer the rocker sole shoes investigated in this study) with a proposed research protocol to determine whether rocker sole shoes influenced chronic low back pain – a claim made by the footwear company. Masai GB Limited agreed to fund the proposed trial. At this point JL approached Siân MacRae (SM) with regards to SM developing and conducting the trial as a PhD research project. Conducting a pilot study was a requirement of the funding agreement for this research. Furthermore, the pilot study was conducted to inform the design of the main clinical study in terms of: sample size calculation; integrity of the study protocol; acceptability and practicality of data collection methods; the randomisation process; recruitment and consent; and selection of the most appropriate primary and secondary outcome measure. The recruitment of participants into the pilot study occurred between January 2008 and November 2008. A reliability study to determine the reliability of the chief investigator (C.I.) to measure spinal impairment measures (secondary outcome measures in the main study) recruited patients in June 2009.

The recruitment of participants into the main clinical study occurred from April 2009 to December 2010. Following commencement of the main clinical study, SM felt it important to determine, if changes in outcome measures were obtained in the rocker sole group compared to the flat sole group, whether biomechanical mechanisms may be a contributing factor to such changes. Hence, SM conceived a series of biomechanical studies to help explain any clinically significant changes that may have occurred as a result of the intervention. Subsequent to attaining ethical approval, these studies ran concurrently with the main study, commencing during the latter part of the main study recruitment period. The recruitment period for the biomechanical studies occurred from June 2010 to December 2010. The Gantt chart in Figure 3.1 demonstrates the thesis time-line.

The roles of all contributors to thesis are presented in *11.1 (p222).*

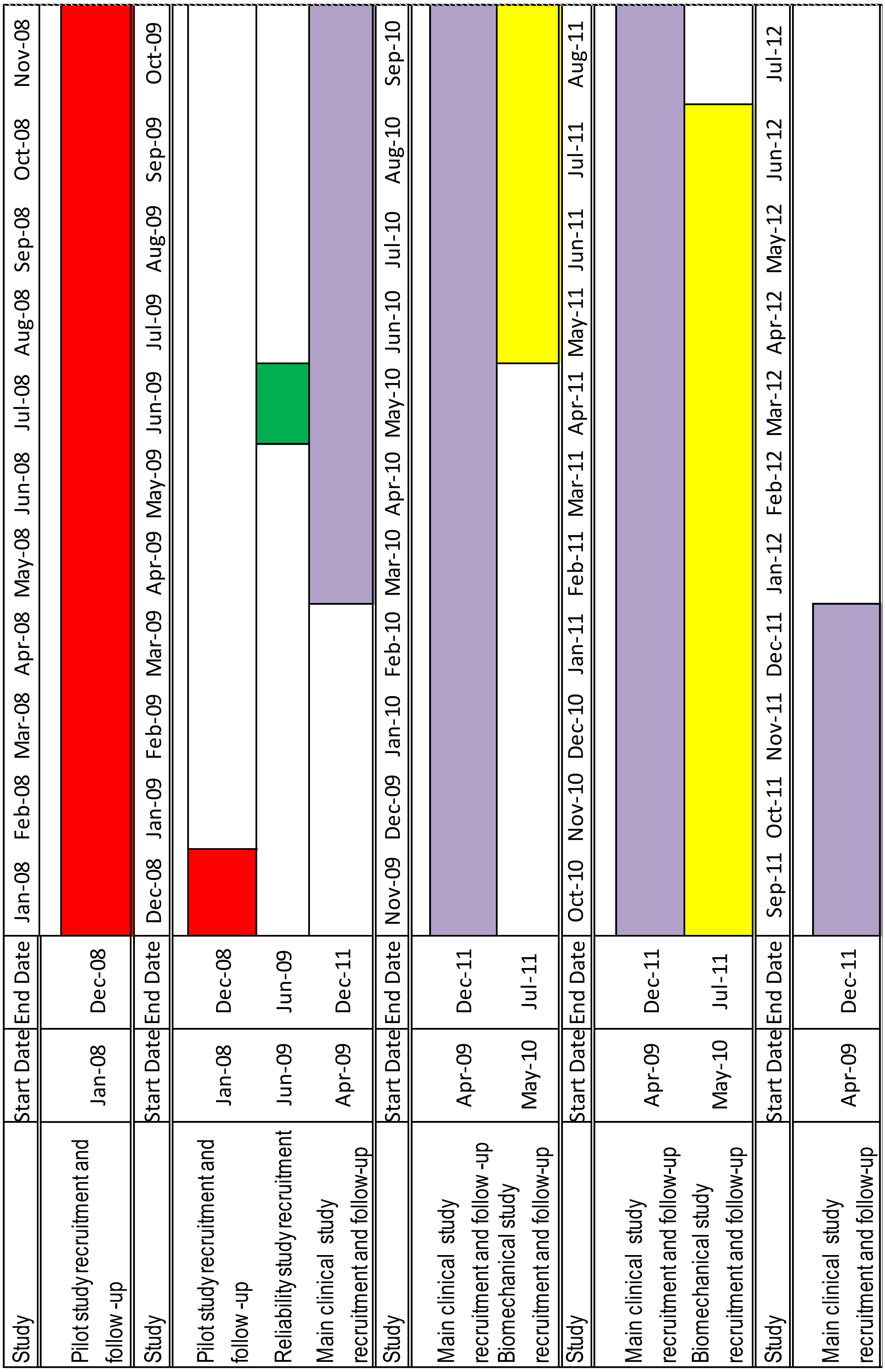


Figure 3.1 Gantt chart demonstrating time-line of studies conducted within the thesis

4 Development of Methodologies for main clinical study

4.1 Aim of chapter

This chapter describes the development of the methods employed in the main clinical study. Two preparatory studies were conducted to inform methodologies: i) a pilot study; and ii) a reliability study for the assessment of spinal posture and impairment (secondary outcome measures in the main clinical study). Adaptations of pilot study methods to improve the main clinical study are presented following reflection on study successes and challenges. Reasons underpinning i.) the choice of primary and secondary outcome measures and ii.) the choice of statistical tests in the main study are discussed.

4.2 Pilot study

4.2.1 Introduction

The pilot study was conducted to inform the design of the main clinical study in terms of: sample size calculation; integrity of the study protocol; acceptability and practicality of data collection methods; the randomisation process; recruitment and consent; and selection of the most appropriate primary and secondary outcome measures. Conducting a pilot study was a requirement of the funding agreement for this research.

4.2.2 Methods

4.2.2.1 Design

This randomised controlled study design was prospective with repeated measures at baseline and six weeks. The co-researcher (Dr Jeremy Lewis (JL)) remained blind to participant group allocation.

4.2.2.2 Participants

Ethical approval for the study was granted from the Riverside Research Ethics Committee (REC reference number: 07/H0706/74). Twenty participants were recruited from general practitioner and consultant referrals to the Neuro-musculoskeletal Physiotherapy Department at the Chelsea and Westminster Hospital, London. Participants were suitable for inclusion if they fulfilled the inclusion and exclusion criteria (Table 4.1).

Table 4.1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Aged 18 to 65 years • A three month or greater history of low back pain • Lumbosacral pain with or without referral (of a supposed non-radicular nature) • Pain of a mechanical nature (pain aggravated or eased by activity) • Willing to comply with the randomisation process. • Able to fully communicate in English • Able to participate in an exercise group and perform exercises at home	• Constant pain • Non-mechanical pain (pain not aggravated or eased by activity or posture) • Nerve root entrapment accompanied by neurological deficit • Neoplasms • Severe structural deformity or osteoporosis • Known spondylolysthesis or spinal stenosis • Fracture of the spine within the past year • Inflammatory disease of the spine • Spinal infection • Severe cardiovascular or metabolic disease • Pregnancy • Previous spinal surgery • Known Morton's Neuroma • Skin ulceration over the foot • Peripheral neuropathy with loss of sensation • History of falls • Surgery to the lower limb in the past 8 weeks • History of deep vein thrombosis (DVT) yet to be stabilised/yet to be advised to return to exercise by their medical practitioner • Unresolved legal issues regarding their back pain • Participants who have previously used rocker sole shoes

4.2.2.3 Outcome Measures

The primary outcome measure in the pilot study was the Oswestry Disability Questionnaire (ODQ) version 2.0 (a questionnaire to assess self-reported low back disability) *(11.2, p224).* The secondary outcome measures used are shown in Table 4.2.

Table 4.2 Secondary outcome measures

Secondary outcome measures
• Roland Morris Disability questionnaire (RMDQ) (a questionnaire to assess self-reported low back disability) *(11.3, p225)*
• SF36 health questionnaire (a measure of health related quality of life) *(11.4, p227)*
• Numerical rating score for pain
• Tampa Kinesiophobia Scale (a questionnaire measuring fear of movement and fear of (re)injury during movements) *(11.5, p231)*
• Hospital Anxiety and Depression Score (a questionnaire measuring anxiety and depression) *(11.6, p232)*
• Range of spine movement (flexion, extension, left and right side flexion)
• Straight leg raise
• Hours study shoes worn per day

4.2.2.4 Consent and Randomisation.

Patients who fulfilled the inclusion and did not fulfil the exclusion criteria were asked to read the Patient Information Sheet *(11.7, p234)* before consenting to take part in the study. They were advised to discuss their participation in the study with family, friends, other healthcare workers, and their physiotherapist before deciding whether or not to participate.

Patients happy to participate were consented into the study by the Chief Investigator (C.I. Siân MacRae). Those signing consent forms *(11.8, p241)* were then assigned by block randomisation (blocks of four), into one of two groups:

- Group 1: Participants received a pair of rocker sole shoes and attended eight back exercise group sessions over four weeks
- Group 2: Participants received a pair of flat sole shoes and attended eight back exercise group sessions over four weeks

The block randomisation protocol was chosen in order to ensure the numbers of participants in each group were similar. Possible combinations for a block size of four with two rocker sole shoe and two flat sole shoe allocations per block was calculated as six. These blocks were written on pieces of paper by Dr Matt Morrissey (original PhD supervisor before he left King's College London), then randomly selected in order to determine the group allocation of all 20 participants taking part in the study. The C.I. was informed of the participant's group allocation by Dr Matt Morrissey once a baseline assessment appointment had been booked.

4.2.2.5 Assessment procedure

The C.I. supervised each participant whilst outcome measure questionnaires were completed. The C.I. then fitted each participant with their allocated study shoes, instructed them in the correct walking and standing technique whilst wearing the shoes (approximately twenty minutes duration), and explained how to complete the diary sheet *(11.9, p243)* regarding number of hours of study shoe wear per day. The co-researcher, blind to group allocation, recorded the spinal impairment measurements (range of motion into flexion, extension, left and right side flexion, and left and right straight leg raise (SLR)). The methods used for assessing lumbar movement have been demonstrated to be reliable by the C.I. (van Blommestein et al., 2012) and by other research (Lewis et al., 2005). Participants, standing barefoot, with their feet hip width apart, were asked to lean forwards, then backwards, then to each side, until they either reached the limit of their available movement, or until their low back pain started to present or worsen. Using a non-stretch tape measure the distance between the patients' left middle finger fingertip and the floor directly below the left medial malleolus was recorded for the flexion and extension movements; for the side flexion movements the ipsilateral middle fingertip and the floor just behind the lateral malleoli were used as marker points for measurement recording. Three readings for each movement were taken and the average used in the data analysis. In order to assess SLR, an Isomed inclinometer (Figure 4.1) was placed on the tibial tuberosity and the patients' leg passively raised by the co-researcher. Participants were asked to report when they would like the co-researcher to stop raising their leg. This could be due to a strong stretching sensation in the posterior aspect of their leg, or if their symptoms of low back pain presented, or worsened. At this point, the SLR movement was stopped, a Numerical Rating Score (NRS) for pain was ascertained from the patient (from 0 to 10, where 0 = no pain, and 10 = worst imaginable pain, and their leg lowered back to the plinth by the assessor. Three readings were recorded for the SLR angle for each leg, and the average documented. The study conducted to investigate reliability of these measurement techniques is described in *4.4 (p53).*

<u>Figure 4.1 Isomed inclinometer</u>

4.2.2.6 Interventions

Baseline assessment occurred one week before participants started the back exercise group in order to allow the participants to gradually wear in their new shoes. During this adaptation week participants were given instruction to gradually increase the time the study shoes were worn each day, initially wearing for only 15 - 30 minutes, progressing to a minimum wear of two hours per day (whilst standing and walking) before attendance at their first exercise group. The back exercise group was an established programme that had been running for approximately three years at the Chelsea and Westminster Hospital, London, UK. The programme involved education, advice and a ten station exercise circuit. Each class was approximately one hour in duration. Participants were asked to attend the group twice a week for a period of four weeks (a total of eight sessions). Study participants were requested to wear their study shoes during the exercise group, and for a minimum of two hours per day during the six week duration of the pilot study.

At the end of their last exercise group participants were re-assessed. The assessment involved the same questionnaires (conducted by the C.I.) and physical tests (conducted by the co-researcher) as performed at baseline. To ensure the co-researcher remained blind to participant group allocation, study shoes were kept out of sight of the co-researcher whilst the spinal measurements were assessed. This point marked the end of each participant's involvement in the pilot study.

4.2.2.7 Adverse events

Adverse events were defined as an increase in pain or symptoms within one week of commencing an intervention (the 'adaptation week' for initial shoe wear, and a participants first week of attendance at the low back exercise group) that required general practitioner or casualty consultation as reported to the investigator (Hay et al., 2005).

4.2.2.8 Data analysis

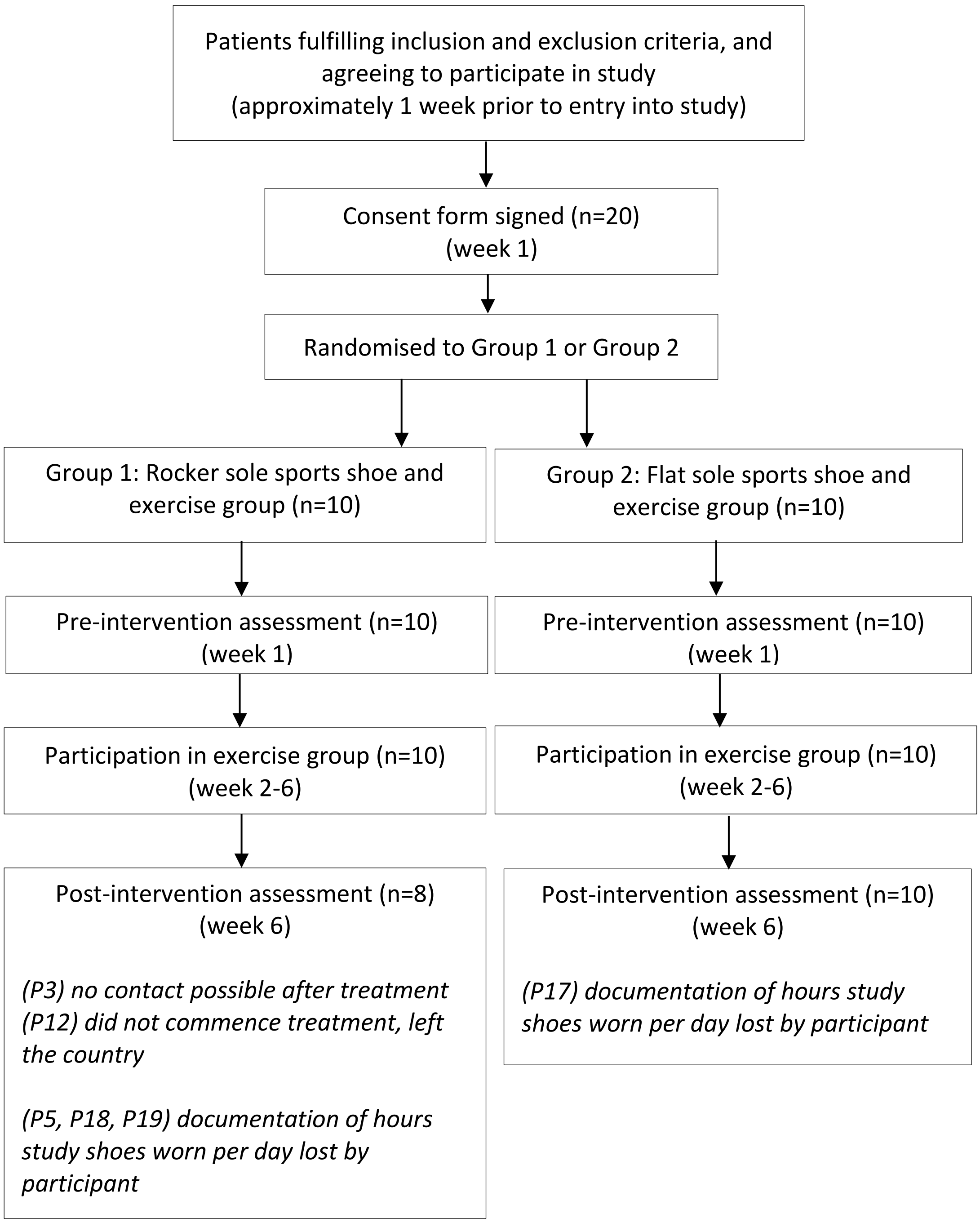
Distributions were checked to see if normal distributions had been met, if this was not the case, non-parametric test were performed. The primary analysis was by intention to treat, including all eligible randomised participants who provided follow-up data. Independent t-tests for parametric data, were applied to determine differences between groups at baseline. Mixed ANOVAs were conducted with one within-subject factor (assessment time points) and one between group factor (footwear type) to compare the effectiveness of shoe type over time (rocker sole shoes versus flat sole shoes).

Data were analysed using IBM SPSS (Statistical Package for the Social Sciences) 20.0.0 (IBM, New York). Results are presented as means (standard deviations [SD]) unless otherwise stated.

4.2.3 Results

Participant entry into the study, randomisation, and participant retention including participants lost to follow-up at each stage of the investigation are presented in Figure 4.2. Twenty participants (nine males, eleven females) with a mean age of 42 years (SD 10.5, range 24 to 60 years) and a mean duration of 5.0 years (SD 6.1, range 0.3 to 20.0 years) of low back pain symptoms were recruited. Table 4.3 presents demographic data and primary outcome at baseline for the two groups. The flat sole shoe group presented with greater disability than the rocker sole shoe group at baseline. Table 4.4 presents the pain and disability outcome measures at baseline and follow-up.

Figure 4.2 Progression of participants through the trial



(P: participant; n: number of participants)

Table 4.3 Participant demographics and primary outcome at baseline

	Rocker sole shoe (n=10)	Flat sole shoe (n=10)	P - value
Age [years]	37.5 (8.6)	46.6 (10.7)	0.05
Height [cm]	174.1 (13.4)	169.5 (9.1)	0.38
Body Mass [kg]	80.0 (16.1)	77.1 (21.9)	0.72
Duration of symptoms [years]	5.5 (6.9)	4.5 (5.7)	0.71
Gender : male : female	6 (60%)* 4 (40%)*	3 (30%)* 7 (70%)*	0.18
Oswestry disability questionnaire [points]	23.4 (11.9)	37.4 (12.3)	0.04

Summary measures represent means (SD) or *numbers (percentages)

Table 4.4 Pain and disability measures at baseline and follow-up

Outcome measure	Rocker sole shoe (n=8)		Flat sole shoe (n=10)		P - value
	Baseline	6 weeks	Baseline	6 weeks	
Oswestry Disability questionnaire (ODI) [0-100, where 0 represents no disability]	20.8 (11.2)	19.3 (12.4)	37.4 (15.3)	24.6 (17.2)	0.10
Roland Morris Disability questionnaire (RMDQ) [0-24, where 0 represents no disability]	5.8 (3.3)	4.1 (2.5)	9.0 (4.9)	5.5 (5.2)	0.24
Numerical rating score for pain (NRS) [0-10, where 0 represents no pain]	7.4 (1.7)	4.8 (1.5)	7.3 (1.6)	3.5 (2.3)	0.27

Summary measure represent means (SD). Between group analysis with mixed ANOVA

No between group differences were detected for change in disability or pain at six weeks compared to baseline (ODQ: $F(1, 16) = 3.07$, $p = 0.10$, $\eta^2 = 0.16$; RMDQ: $F(1,16) = 1.52$, $p = 0.24$, $\eta^2 = 0.09$; NRS: $F(1,16) = 1.30$, $p = 0.27$, $\eta^2 = 0.08$).

4.2.3.1 Duration of recruitment period

Recruitment of participants into the pilot study occurred over an eleven month period. This recruitment period continued longer than had been anticipated due to the rate of recruitment.

4.2.3.2 Acceptability of participant assessment

When completing the Oswestry disability questionnaire participants generally took longer and asked more questions to the C.I. than when completing the Roland Morris Disability Questionnaire. At times explanations by the C.I. were lengthy, hence increasing the time participants were in a seated position - an aggravating factor for many. The Roland Morris Disability Questionnaire presented little time or difficulty to complete.

The SF36 Health-related quality of life questionnaire was time consuming for participants to complete. This again increased the duration of time participants were in a seated position.

All other outcome measures were assessed or completed with no reported problems or concerns from participants or assessors.

4.2.3.3 Participant attrition

An acceptable number of participants who entered the study also attended the six week assessment. Ten per cent of participants (two participants) did not attend their final review – one participant left the country between consent into the study and commencement of the exercise class, and the second participant was lost to follow-up due to an inability to contact them by phone or letter. In addition to the participants lost to follow-up, three participants reported losing their study diary sheets, documenting hours of shoe wear per day. Twenty-five percent of participants' 'adherence to shoe use' data was missing; the CI did not have confidence in the data, hence it was not presented.

4.2.3.4 Acceptability of the interventions

Feedback from referring physiotherapists indicated that one reason that potential participants declined to take part in the study was their inability to attend the back exercise classes due to the classes running mid-morning. Patients suggested that an early morning class would be more convenient to attend.

Further feedback from patients unable to commit to the exercise classes identified that attending a class twice a week was not possible due to other commitments, for example, gaining time off work. They reported that a required class attendance of once a week would have enabled them to participate.

4.2.3.5 Success of participant randomisation

Equal numbers of participants were randomised into each footwear group. However, at baseline, demographic data demonstrated a failure in the randomisation process to produce two matched groups for many of the parameters of interest. Differences in age, gender and disability are evident. This was most likely due to the small sample size of the pilot study.

4.2.4 Discussion

This pilot study suggests that change in pain and disability at six weeks follow-up, following attendance at a back exercise group, was similar for people wearing rocker sole and flat sole shoes. However, the pilot study had a small sample size and demonstrated less than optimal group randomisation, hence findings should not be generalised to the general population.

The pilot study proved valuable in demonstrating study feasibility, limitations in the study design and the degree of acceptability of the intervention to participants. This enabled alterations of the planned methodology to be put in place, ensuring the main study to be a more robust and higher quality RCT. The planned alterations form the body of this discussion.

4.2.4.1 Alterations in outcome measures for the main clinical study

The use of the Oswestry Disability Questionnaire has been recommended for back pain patients who are likely to have severe persistent disability, whereas the Roland Morris Disability Questionnaire has been recommended for back pain patients who are likely to have relatively less disability (the population expected to be recruited into the main study)

(Roland and Fairbank, 2000). The Roland Morris Disability Questionnaire has been shown to be reliable and valid (Roland and Morris, 1983) and responsive to change over time (Boulter et al., 1998). It was therefore decided to replace the Oswestry Disability Questionnaire with the Roland Morris Disability Questionnaire as the primary outcome measure in the main clinical study *(4.3.4.1, p46).*

The SF36 health-related quality of life questionnaire was lengthy and time consuming for participants to complete. Furthermore, the SF36 subscales have been demonstrated to show a floor effect for those patients who deteriorate, hence for those reporting worsening health, SF36 subscales may not adequately reflect changes in their health status (Suarez-Almazor et al., 2000). It was therefore decided to replace the SF36 health-related quality of life questionnaire with the EuroQol 5D (EQ-5D) health-related quality of life questionnaire *(11.10, p245)* for the main clinical study *(4.3.4.3, p47).*

4.2.4.2 Duration of participant recruitment

Due to the extended length of the recruitment period, alterations to recruitment protocol with a view to improving the rate of recruitment into the main study would be necessary. A multi-site study may allow for a greater number of appropriate participants to be recruited over a shorter period of time compared to recruitment from the originally planned single site.

4.2.4.3 Alteration to exercise group accessibility

In an aim to improve participant accessibility to the low back exercise group, class timings were altered. It was anticipated that this would offer patients a wider variety of potential attendance times which may increase recruitment into the main research study.

Furthermore, potential participants had reported that it would not be possible to attend two exercise classes each week. Reducing the number of exercise sessions each participant would be required to attend whilst adhering to the NICE guideline recommendations (NICE, 2009) (which states that a CLBP exercise programme “should consist of a maximum of eight sessions over a period of up to twelve weeks”) may increase the recruitment rate.

4.2.4.4 Participant acceptability of interventions and study documentation

Eighty per cent of participants completed the study and no informal negative feedback was gained from these eighteen participants regarding footwear use or exercise class participation. This suggests that the interventions of exercise class attendance and footwear use, and the reassessment at six weeks were acceptable. Three participants, however, reported losing their study diary sheets. Clarification of diary sheet wording and clearer explanation to participants when describing how these sheets should be completed may assist in an increased percentage return of these documents at follow-up assessments in the main study.

4.2.4.5 Appropriate sample size calculation

One purpose for conducting the pilot study was to inform the main study of an appropriate sample size. Standard deviation data for the Roland Morris Disability Questionnaire obtained in the pilot study in addition to the minimal clinically important difference for the Roland Morris Disability Questionnaire in the CLBP population (reported in previous research (Maughan and Lewis, 2010)) were used to inform the sample size for the main clinical study.

4.2.5 Conclusions

Conducting the pilot study highlighted certain aspects of the planned main study methodology that may benefit from change, in order to improve study design, namely:

- Reducing the frequency of exercise class attendance from twice to once a week to improve recruitment rate.
- Providing a greater range of exercise class times may improve recruitment rate
- Conducting the research at more than one site may improve recruitment rate
- Reviewing the clarity and ease of completion of the study diary sheet may increase the number of diary sheets returned
- Alteration of outcome measure choice to improve i.) ease of completion by participants and ii.) suitability to sample population

4.3 Methodological considerations for main clinical study

Conducting the pilot study *(4.2, p33)* identified several methodological concerns requiring amendment in order to improve the main clinical study design. This section describes alterations made to the main study methodology, and the justification for choice of outcome measure and statistical tests in the main clinical study.

4.3.1 Alterations to the participant recruitment protocol

Due to the extended length of the recruitment period in the pilot study, several methodological alterations were implemented with a view to improving the rate of recruitment into the main study. It was decided that a multi-site study incorporating five sites, may allow for a greater number of appropriate participants to be recruited over a shorter period of time compared to recruitment from the originally planned single site. Four additional sites in south west London were identified and meetings were held with departmental leads at each of the proposed sites to explain the study and determine whether each site would be happy to host the trial. All sites approached were happy for their physiotherapy departments to be involved. The additional four sites were:

- Balance Performance Physiotherapy, Clapham, London SW4
- Kingston Hospital, Kingston, Surrey KT2
- St. George’s Hospital, Tooting, London SW18
- Queen Mary’s Hospital, Roehampton, London SW14

4.3.2 Method of randomisation chosen for the main trial

Equal numbers of participants were randomised into each footwear group utilising the block randomisation method chosen in the pilot study. Therefore, this block randomisation protocol (blocks of four) was chosen for the main clinical study in order to ensure the numbers of participants in each group at each recruitment site remained similar.

4.3.3 Justification for selection of assessment time points in the main clinical study

Baseline, six weeks, six months and one year were selected as assessment time points for participants in the main clinical study. The six week assessment aimed to detect combined change in outcome measures corresponding to completion of the back exercise class and early use of study footwear. The six month assessment aimed to detect outcome measure changes occurring following the prolonged use of study shoes. Primary outcome point occurred at one year from baseline to provide adequate follow-up time for such a chronic, recurrent and fluctuating condition.

4.3.4 Justification for selection of outcome measures assessed in the main clinical study

No single outcome measure accurately reflects the effects a treatment programme may have on all areas of a patient's life (McIlveen and Robertson, 1998). The World Health Organisation (2000) states that the health of an individual is based on three categories; impairment, activity and participation. Appropriate outcome measures should be assessed for each of these categories. In CLBP, the assessment of psychosocial and physical aspects are of particular importance (Hope, 2002; Staal et al., 2002). There is currently no 'gold standard' group of outcome measures for the assessment of CLBP. However, it is considered satisfactory to include outcomes assessing three or more of the following five categories in CLBP research trials; back specific function, generic health status, pain, work disability and satisfaction with care/intervention (Bombardier, 2000; Deyo et al., 1998; Dworkin et al., 2005). Outcome measures assessed in the main clinical study are presented below.

4.3.4.1 Self-reported disability

The Roland Morris Disability Questionnaire (RMDQ) *(10.3, p225)* consists of twenty four statements selected from the Sickness Impact Profile (Bergner et al., 1981) and adapted to determine how a person's back pain may affect activities of daily living. Participants completing the RMDQ are asked to tick a statement if it applies to them 'today'. Outcome scores range from 0 (no disability) to 24 (severe disability). During the pilot study the Roland Morris Disability Questionnaire (RDQ) presented little difficulty for participants to complete. The questionnaire has a high sensitivity in CLBP participants with lower disability scores (the population expected to be recruited into the main study) (Roland and Fairbank, 2000). The RMDQ has been shown to be reliable, valid (Roland and Morris, 1983) and responsive to change over time (Boulter et al., 1998) in a CLBP population.

4.3.4.2 Self-reported pain

The Numerical rating score for pain asks patients to verbally rate their pain intensity on an eleven point scale where zero represents ‘no pain’ and ten indicates ‘worst imaginable pain’. It has been demonstrated to be responsive to change in chronic low back pain populations (Pengel et al., 2004).

4.3.4.3 Health related quality of life

The EQ-5D-3L (or EuroQol) is a generic preference-based tool for the measurement of self-reported health-related quality of life *(11.10, p245)* (Brooks, 1996). The EQ-5D-3L has two components. The first component evaluates five domains: mobility, self-care, activity, pain and depression and anxiety (the latter two domains are evaluated together). Each domain has three possible levels: no impairment, mild to moderate impairment, and severe impairment. The second component is the EQ-VAS (visual analogue scale) ranging from 0 to 100 where zero represents ‘worst imaginable health’ and 100 ‘best imaginable health’. The EQ-5D-3L demonstrates high reliability when re-tested over time (Centre for Health Economics, 1994). The generic EQ-5D-3L visual analogue scale component has been found to perform better than most SF36 subscales (the health-related quality of life questionnaire assessed in the pilot study) in discriminating among those who improved and those who became worse in a LBP population (Suarez-Almazor et al., 2000). A further advantage of the EQ-5D-3L is its ease of completion by participants.

4.3.4.4 Fear of movement

Fear avoidance, the avoidance of movement or activities based on fear, has been proposed as a central mechanism in the development of chronic back problems (Vlaeyen and Linton, 2000). Hence, when assessing changes in disability and pain experience, fear-avoidance beliefs are an important measure to monitor. Previous studies in patients with chronic and acute LBP have demonstrated that fear-avoidance beliefs are predictive of disability and work status (Fritz et al., 2001; Vlaeyen and Linton, 2000; Waddell et al., 1993).The Tampa scale of Kinesiophobia *(11.5, p231)* (a questionnaire assessing fear of movement and (re)injury) requires patients to rate seventeen items on a four point scale ranging from ‘strongly agree’ to ‘strongly disagree’. Total scores range from 17 to 68, with higher scores reflecting a greater fear of movement or (re)injury. The scale possesses good psychometric properties, is a reliable measure (Woby et al., 2005) and offers well-established construct and predictive validity (Vlaeyen and Linton, 2000) in the back pain population.

4.3.4.5 Anxiety and depression

Back symptoms are frequently accompanied by depression or anxiety and psychological distress (Kinney et al., 1993; Rush et al., 2000). Anxiety may increase pain perception leading to less than optimal coping behaviours (Adams et al., 1994; Simmonds et al., 1996). Hence, outcome measures to assess such bio-psychosocial influences on a patient’s recovery should be included in CLBP research. The Hospital Anxiety and Depression Scale (HADS) *(11.6, p232)* is a reliable and valid measure for assessing anxiety and depression in medical patients (Herrmann, 1997); the depression subscale has established validity and reliability (Greenough and Fraser, 1991) for an inpatient CLBP population - the reliability of the HADS has yet to be demonstrated in an out-patient setting for CLBP patients. The anxiety and depression sub-scales consists of seven questions each (a total of fourteen questions). Each question is scored on a four point scale from 0 to 3. Scores can range from 0-21 with higher scores reflecting greater anxiety and depression.

4.3.4.6 Restoration of functional activity

The Patient Specific Functional Score (PSFS) is a questionnaire used to quantify a participant’s activity limitations *(11.11, p247)*. A participant may improve functionally but show little or no change in their level of impairment (Beattie and Maher, 1997; Waddell et al., 1992), hence, it is considered important to investigate restoration of activity and participation despite levels of pain and disability (Liddle et al., 2004). Although the RMDQ, the primary outcome measure in the main study, measures self-reported function, it is not patient specific; hence the PSFS may be more sensitive to detect an individual’s change than the RMDQ (Pengel et al., 2004). In CLBP patients the patient specific functional scale has demonstrated moderate to excellent reliability, validity and sensitivity to change (Maughan and Lewis, 2010; Stratford, 1995).

4.3.4.7 Patient satisfaction

A simple global measure of patient satisfaction towards the study shoe they received was assessed (Hudak and Wright, 2000). The C.I. asked participants at six months and at one year “How satisfied are you with the study shoes you have received?’ Participants were asked to rate their satisfaction on a scale from 1 (extremely dissatisfied) to 7 (extremely satisfied) *(11.12, p248).*

4.3.4.8 Impairment measures

In studies investigating rocker sole shoes in asymptomatic participants a reduction in the degree of trunk flexion, both in standing (New and Pearce, 2007) and during locomotion (Vernon et al., 2004), has been reported. This is suggestive of a more upright posture. The main study will investigate whether a change in thoracic kyphosis angle in barefoot standing occurs following the use of either shoe type and, if changes do occur, whether these potential changes correlate with changes in other outcome measures such as reduction in pain or disability. The assessment method for measuring thoracic kyphosis angle demonstrated excellent clinical reliability for intra-rater re-assessment by the C.I. *(4.4, p53).*

The assessment of spinal impairment measurements by the C.I. demonstrated excellent reliability *(4.4, p53).* These measurements (spinal flexion, extension, left and right side flexions and left and right straight leg raise angles) will be recorded in the main clinical study. It is acknowledged that although such physical impairment measures are routinely measured in clinical practice and clinical research, their low responsiveness (Pengel et al., 2004) (the ability of an outcome measure to detect clinically important change in a patient’s health status over time) indicates that this approach is not optimal for assessing change over time in those with CLBP. However, these measures were included in the main clinical study to determine, if changes do occur between shoe groups, whether a sub-group demonstrating baseline movement restriction or pain provoked by a particular movement may influence outcome.

4.3.4.9 Primary outcome measure

The Roland Morris disability questionnaire was chosen as the primary outcome for the main clinical study.

4.3.5 Justification for the methods and statistical analysis chosen to analyse data in the main clinical study

4.3.5.1 Removal of outliers

Box plots enable visual comparisons of interquartile ranges, medians, and group ranges of data between groups to be made. In addition, box plots highlight the presence of 'outliers' – an observation very different from most other observations with the potential to bias statistics (Field, 2009). The presence of outliers may represent incorrect data entry or the inclusion of a variable that represents an extreme case within the population studies (Field, 2009; Sim and Wright, 2000). When analysing the primary outcome, recalculation of study data occurred following removal of any outliers to determine whether extreme cases influenced the results.

4.3.5.2 Analysis of variance

Analysis of variance (ANOVA) is an appropriate method to statistically analyse the difference in mean values for one or more data sets when assessed under two or more experimental conditions (Field, 2009). Distributions within groups must be normally distributed to meet the requirements of an ANOVA test: variances in each experimental condition must be similar; observations must be independent; and the dependent variable must be measured on at least an interval scale (Field, 2009). A repeated measures factorial design ANOVA and mixed design ANOVA was selected as an appropriate method to statistically analyse within group and between group differences, respectively, for each shoe group across four assessment time points (Field, 2009). Macuhly test of sphericity assumption and Levene's test of equality of variances assumption were considered for within-subject and between-subject effects, respectively (Field, 2009). In the presence of significant effects, multiple comparisons were made using the Bonferroni method (Field, 2009). This method is conservative, reducing the probability of a type one error, although the probability of a type two error may be raised. Analysis of covariance (ANCOVA) is the recommended analysis to perform when taking into account a variable thought to influence a dependent variable (Field, 2009). In the treatment of CLBP, baseline disability has been shown to influence the level of change observed in disability following an intervention (Stratford et al., 1998). Therefore, in the main clinical study, an ANCOVA was selected as an appropriate method to statistically analyse between group differences for each shoe group across the three reassessments points whilst taking into account differences in baseline disability between the groups (Field, 2009).

4.3.5.3 Independent t-test

To determine whether randomisation of participants between groups had been effective, baseline demographic and outcome measure data were compared between groups. An independent t-test is an appropriate method to statistically analyse the difference in mean values between two groups, when participants in each group are different, and where the assumption of normality is met (the variances of populations are similar and scores are independent) (Field, 2009).

4.3.5.4 Pearson's Chi-square test

A Chi-square (χ^2) test is an appropriate method to statistically analyse the presence of a relationship between two categorical variables (Field, 2009). Data must be independent, and expected frequencies must be greater than five in order to meet the assumptions of the Chi-square test (Field, 2009). Chi-square was used to assess the differences between the shoe groups regarding the number of participants reporting minimal clinically important differences in the primary outcome, and the number of participants very or extremely satisfied with the study shoes they received.

4.3.5.5 Replacing missing values

The presence of missing data may be a problem when conducting repeated measure ANOVAs due to the exclusion of any data sets with a missing value from the analysis. In a small sample these exclusions may result in remaining data sets being too few to have sufficient power to detect effects. SPSS has a specific package for evaluating missing data (IBM, 2011). Replacing missing values with predicted values allows the analysis of a complete data set which may be more powerful to detect change than analysing incomplete data sets. In the main study, missing values were replaced only for the primary outcome measure – the Roland Morris Disability Questionnaire. To demonstrate that data in the main clincial study were missing at random Little's 'Missing Completely at Random' test was conducted. Little's test examines the hypothesis that data are missing completely at random - an assumption that must be satisfied prior to replacing missing values with imputation techniques. Missing numbers were then replaced using the Expectation-Maximisation technique (Dempster et al., 1977) within the Missing Number Analysis function in SPSS (IBM, 2011).

4.3.6 Calibration of measuring devices

To ensure that the length of the 'non-stretch' tape measure did not change with repeated use the C.I. checked the accuracy of the tape measure once a month by comparing the centimetre scale on the tape with a metal metre ruler. To ensure accuracy of the inclinometer the C.I. calibrated the inclinometer scale (displayed in 2 degree divisions) against an electrical inclinometer (Saunders Digital Inclinometer; the Saunders Group, Chaska, Minnesota, USA), the accuracy of which has been demonstrated to be +/- 0.1 degree.

4.4 Intra-rater reliability study for the assessment of thoracic kyphosis angle, lumbar impairment measures, and straight leg raise

4.4.1 Introduction

This study was conducted to investigate the intra-rater reliability of the chief investigator (Siân MacRae) in the assessment of thoracic kyphosis angle, straight leg raise (SLR) angle, and the lumbar impairment measures of flexion, extension, and left and right side flexion. These are secondary outcome measures in the main clinical study *(Chapter 5, p61).* This study has been accepted for publication (van Blommestein et al.,2012) *(11.13, p249).*

4.4.2 Methods

4.4.2.1 Design

This study employed a single-examiner, same-subject, repeated measures design. Participants were assessed on two occasions.

4.4.2.2 Participants

This study was approved by the Research Ethics Subcommittee at King's College London (BDM/08/09-85) *(11.14, p255).* Participants were recruited via email *(11.15, p257)* using the Kings College London website and by verbal invitation at Guy's Campus. Inclusion criteria involved male and female volunteers aged 18-65 years, and a straight leg raise (SLR) of 40 degrees or more prior to first perceived onset of stretch. Exclusion criteria were: any indication of lower limb neurological compromise; a history of thoracic pain, low back pain, or lower limb problems over the past six months that required medical attention; limitation of movement of the hip or knee; scoliosis; chest conditions such as asthma, chronic bronchitis and emphysema; pregnancy; any systemic illness; and an inability to give informed consent.

4.4.2.3 Measurements

The measures assessed in this study were thoracic kyphosis angle, left and right SLR angle, and the spinal impairment measures of flexion, extension, and left and right side flexion. Each measure was assessed using an Isomed gravitational inclinometer (Isomed, 975 Sandy Blvd., Portland, OR 97214) *(Figure 4.1, p37).*The thoracic kyphosis angles and lumbar impairment measures were assessed with the participant in standing and the SLR angle measured with the participant lying supine on a plinth.

4.4.2.4 Assessment of participants

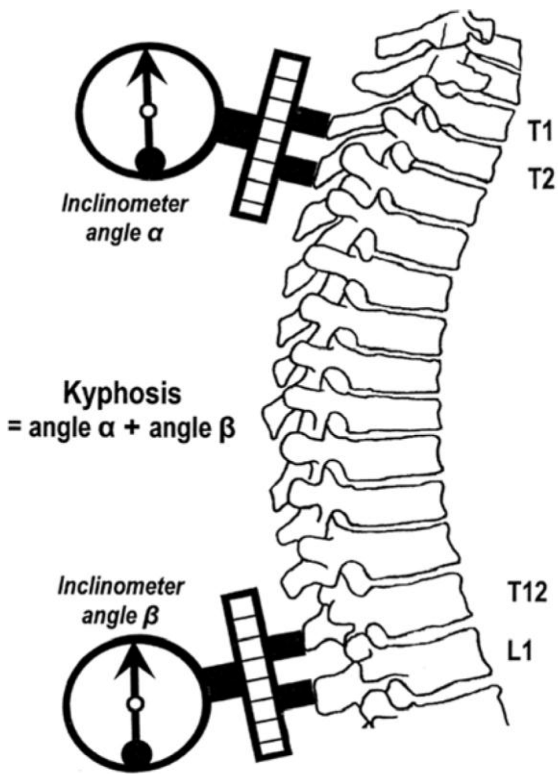
All testing was performed in a private room at Guy's Campus, King's College London. On the testing days, the room temperature and lighting were kept constant and noise levels were kept to a minimum to prevent distraction.

Individuals who agreed to participate, met the inclusion criteria, and did not fulfil the exclusion criteria attended two assessments, approximately one hour apart. At initial assessment participants were given a full explanation of the testing procedure by the co-researcher (Andrew van Blommestein). All participants received a copy of the participant information sheet *(11.16, p258).* Those willing to participate in the study were asked to sign and date the consent form *(11.17, p261).* Participants were required to remove their shoes and socks for the test procedure. All participants were asked to wear short trousers; male participants were asked to remove their shirts; and female participants were requested to wear vest tops. Demographic data of height, body mass, and age were recorded.

Assessment of thoracic kyphosis angles

The angle of thoracic kyphosis was determined by the linear and triangular addition of angles rule (Figure 4.3). This equation simplifies to the kyphosis being equal to the difference between the tangent on the upper level (spinous process of the first and second thoracic vertebra (T1 and T2 respectively) and the tangent on the lower level (spinous process of the 12th thoracic and first lumbar vertebra (T12 and L1 respectively).

Figure 4.3 Calculation of thoracic kyphosis angle (Lewis J.S., with permission).



Participants were asked to adopt a comfortable standing position that felt natural to them. The following standardised instructions were given to each participant:

"Please stand in a position that feels comfortable and normal to you. Slowly bend your head forwards and backwards three times. Stop in a position that feels normal to you. Now gently swing your arms forwards and backwards three times. Let them rest comfortably by your side in a position that feels normal to you. Take three deep breaths and stand in a posture that feels comfortable and normal to you."

Following these instructions, the C.I. identified the relevant spinous processes. To locate the T1 and T2 thoracic spinous processes, the C.I. identified the spinous process of the commonly most prominent seventh cervical vertebra and then palpated distally to find the spinous processes of T1 and T2. To locate the T12 and L1 spinous processes the C.I. first located the iliac crests, and then palpated postero-medially to locate the spinous process of L4. From this level, the C.I. palpated proximally to locate the spinous processes of L1 and T12. Six millimetre diameter adhesive stickers were used to mark the located spinous processes. The pegs of the inclinometer were placed on the pairs of upper and lower thoracic stickers. Three inclinometer measurements were recorded at the upper and lower thoracic spinal levels. Adhesive stickers were then removed.

Assessment of spinal movement

In standing, participants were asked to slide their hands down the front of their legs until they experienced the first point of painful stretch. Using a 'non-stretch' tape measure the distance between the participant's left middle fingertip and the floor directly below the left medial malleolus was recorded for the flexion movement. Lumbar extension measurements involved the participants sliding their hands down the posterior aspect of their legs, keeping knees straight. The distance between the patients' left middle fingertip and the floor directly below the left medial malleolus was recorded for the extension movement. For the left and right side flexion movements participants were requested to slide their hands down the lateral aspects of their left and right legs respectively, without rotating their trunk. The distance between the ipsilateral middle fingertip and the floor just behind the lateral malleoli was recorded. Three readings for each movement were taken and the average used for data analysis.

Assessment of straight leg raise

On completion of the standing measurements, participants were asked to lie supine on a plinth, with arms by their sides, no lateral flexion or rotation at their trunk, and hips in neutral adduction/abduction. A single pillow supported the head and neck to ensure a standardised degree of neck flexion. The participant's spines of scapulae rested on the bottom edge of the pillow. The following standardised instructions were then given:

"Please remain in a relaxed lying position. I am going to slowly lift your leg. If at any time you feel discomfort or would like me to stop please inform me straight away. I will then record the angle of movement and return your leg to the starting position. It is normal to sometimes feel a tightness or stretch behind the knee and into the back of the thigh."

The inclinometer was placed on the most prominent aspect of the tibial tuberosity of the leg to be raised. The C.I. then raised the participant's leg whilst maintaining the position of the inclinometer. When a participant reported the first perceived onset of a strong stretching sensation in the posterior aspect of the raised leg the C.I. recorded the inclinometer angle, and lowered the leg to the plinth. Three readings of SLR angle were recorded for each leg, and the average documented.

Assessment 2

Thoracic kyphosis angle, spinal impairment, and SLR were reassessed as described above. The procedure for assessment 2 replicated assessment 1. The interval between assessments was approximately one hour. This aimed to reduce memory bias by reducing the likelihood of the C.I. recalling participant measurements from assessment 1. To further reduce memory bias, the data collection for one participant was staggered by the assessment of two other participants during the time between the two assessments of the first participant (i.e. three participants were assessed twice over a two hour period). The hour interval between assessments allowed any residual marks left by the stickers on a participant's skin, following the first assessment, to disappear.

4.4.2.5 Data entry

All measurements were relayed verbally by the C.I. to the co-researcher who recorded the results onto an Excel spread sheet. The C.I. was blind to all data between assessment 1 and assessment 2.

4.4.2.6 Sample size calculation

For a power of 0.8 and an alpha of 0.05, for two time points (or two assessments), or two raters, the number of participants required was suggested to be 19 (Portney and Watkins, 2009; Walter et al., 1998). The number of participants recruited into the current study was increased to 30 in order to increase statistical power, and to allow for a loss of participant data and participant withdrawal.

4.4.2.7 Data analysis

Intraclass correlation coefficients (ICC), 95% confidence intervals (95% CI) and standard error of measurement (SEM) were calculated to determine intra-rater reliability (Hicks C., 2004).

Reliability was calculated by analysing the mean value of each measurement at each assessment. ICC model 2 was selected as it was suggested by Portney and Watkins (Portney and Watkins, 2009) to be best suited for generalising the findings of the method of measurement used in this study to clinicians with similar characteristics. ICC models (2,3) for average measures were evaluated using SPSS version 17.0 software (SPSS Inc., Chicago, Il, USA). Options of two-way random and absolute agreement were selected when analysing the single and mean measurements with the SPSS software.

4.4.3 Results

Thirty asymptomatic participants (15 males, 15 females) with a mean age of 33.0 years (SD 11.2, range 23 to 65 years) were recruited. Table 4.5 presents participant demographic data.

Table 4.5 Participant demographics

	Participants (n=30)
Age [years]	33.0 (11.2)
Height [cm]	172.0 (11.0)
Body mass [kg]	72.0 (12.6)
Gender	Male: 15 (50%)* Female: 15 (50%)*
Dominant leg	Right: 27 (90%)* Left: 3 (10%)*

Summary measures represent means (SD) or *numbers (percentages).

Results demonstrate that using the average of three measures for thoracic kyphosis angle, SLR and spinal impairment measures, used as outcome indicators in the main investigation, provide excellent clinical reliability (Table 4.6 and 4.7) (Portney and Watkins, 2009). The values for the SEM of each measure suggested that measurements less than or equal to the values obtained should be considered as measurement error and values above these figures should be considered as real change. Using the 1 SEM, a clinician may assume with 68% certainty that the individual's true score will lie between +/-1 SEM; utilising the 2 SEM scores, increases the certainty to 95% (Portney and Watkins, 2009). For example, if a participant's thoracic kyphosis angle changes by greater than 4.4 degrees from baseline to reassessment, there is only a 5% chance that this change has occurred by chance.

Table 4.6 Intratester reliability of thoracic kyphosis and straight leg raise angle

		Thoracic kyphosis angle	Right straight leg raise angle	Left straight leg raise angle
Mean (SD) [degrees]	Assessment 1	33.1 (8.4)	81.4 (12.2)	80.4 (11.3)
	Assessment 2	32.4 (8.2)	81.2 (12.6)	81.1 (11.9)
Range [degrees]	Assessment 1	14.6-49.3	61.3-105.3	64.0-102.7
	Assessment 2	15.3-46.7	57.3-105.3	64.7-108.0
ICC (2,3)	Average of three measures	0.89	0.97	0.97
	95% Confidence Interval	0.77-0.95	0.93-0.99	0.94-0.99
	SEM/degrees	2.2	2.1	2.0
	2x SEM/degrees	4.4	4.3	3.9

(ICC: intraclass correlation coefficient; SEM: Standard error of measurement.)

Table 4.7 Intratester reliability of spinal impairment measures

		Spinal flexion	Spinal extension	Right spinal side flexion	Left spinal side flexion
Mean (SD) [cm]	Assessment 1	9.3 (9.2)	59.5 (5.7)	44.6 (5.4)	44.8 (5.9)
	Assessment 2	8.8 (9.2)	59.5 (5.6)	44.3 (5.2)	44.7 (5.2)
Range [cm]	Assessment 1	0.0-31.0	45.1-67.7	36.7-58.0	36.4-58.5
	Assessment 2	0.0-32.1	45.2-67.4	37.2-55.7	36.9-56.1
ICC (2,3)	Average of three measures	0.99	0.99	0.99	0.98
	95% Confidence Intervals	0.98-0.99	0.98-0.99	0.98-0.99	0.96-0.99
	SEM [cm]	0.9	0.6	0.5	0.8
	2x SEM [cm]	1.8	1.2	1.1	1.6

(ICC: intraclass correlation coefficient; SEM: Standard error of measurement; cm: centremetres)

4.4.4 Discussion

This reliability study evaluated the intra-tester reliability of clinical methods for measuring thoracic kyphosis, lumbar impairment measures and SLR angles in pain free participants. The measurement techniques employed by the C.I. demonstrated excellent clinical reliability in pain free participants from using an Isomed inclinometer to assess thoracic kyphosis, spinal impairment measures and SLR in asymptomatic participants. Advantages associated with this reliable method of measurement are that it is simple to use, time efficient and inexpensive.

Potential inaccuracies on palpation of anatomical landmarks may have affected the validity of the measurement. Additionally, study participants were 30 asymptomatic adults, with an average age of 33 (SD 11.2) years; therefore, generalisation of these results to individuals who are older, younger or symptomatic must be done with caution.

5 Effectiveness of rocker sole shoes in chronic low back pain

5.1 Chapter summary

This chapter investigates the effects of rocker sole shoes in the management of people with chronic low back pain (CLBP). One hundred and fifteen participants from five research sites were randomly allocated to receive either a flat sole shoe or a rocker sole shoe. Participants were requested to wear their study shoes for a minimum of two hours per day for the duration of the study, and attend a low back exercise group. Participants were assessed at baseline, six weeks, six months and one year. The primary outcome measure, the Roland Morris Disability Questionnaire, assessing self-reported disability, demonstrated no difference in improvement at one year between those allocated to either shoe group.

5.2 Introduction

Low back pain (LBP) is common with a life-time incidence of up to 80% (Airaksinen et al., 2006; Koes et al., 2006); five to twenty percent develop more persistent chronic low back pain (CLBP) (Johanssen et al., 1995; Klaber Moffett et al., 1986; Quittan, 2002; Tortensen et al., 1998). Healthcare costs are consequently substantial (Maniadakis and Gray, 2000).

Although national (NICE, 2009) and international guidelines (Koes et al., 2001) recommend exercise therapy in the management of CLBP, the long-term effectiveness of such an approach appears minimal (Hayden et al., 2005a; UK BEAM Trial Team, 2004). Consequently, novel approaches yet to be investigated in robust randomised controlled trials have been proposed as alternative and effective adjuncts to the management of LBP.

During the past decade, rocker sole footwear have been marketed with persuasive advertising suggesting a positive correlation between wearing this type of footwear and a reduction in low back pain (Masai Barefoot Technology GB Ltd, 2012). Manufacturers claim that the unstable curved sole can positively influence mechanisms associated with CLBP, such as poor balance, poor posture, and reduced capacity to attenuate shock whilst walking (Masai Barefoot Technology GB Ltd, 2011). However, there is a paucity of evidence to suggest these claims are justified. This randomised, controlled trial aimed at determining whether wearing a rocker sole shoe would result in a reduction in disability and pain when compared to wearing a flat sole shoe following a typical exercise treatment for LBP, and in particular, in those who report LBP when standing or walking.

The hypotheses under investigation in this clinical trial are:

Primary *null* hypothesis (H_0):

H_0 1: The addition of a rocker sole shoe to the treatment of chronic low back pain (CLBP) will not result in a significant improvement in disability (Roland Morris Disability Questionnaire) in patients when compared to the addition of a flat sole shoe when assessed at six weeks, six months and one year.

Secondary *null* hypotheses (H_0):

H_0 2: The addition of a rocker sole shoe to the treatment of chronic low back pain (CLBP) will not result in a significant reduction in pain (Numerical Rating Score) in patients when compared to the addition of a flat sole shoe when assessed at six weeks, six months and one year.

$H_0$3: For people reporting pain on standing or walking, there will be no difference in change in disability in people wearing rocker sole shoes when compared to people wearing flat sole shoes at six weeks, six months and one year.

Primary *alternative* hypothesis (H_1):

H_1 1: The addition of a rocker sole shoe to the treatment of CLBP will result in a significant reduction in disability (Roland Morris Disability Questionnaire) in patients with CLBP when compared to the addition of a flat sole shoe when assessed at six weeks, six months and one year.

Secondary *alternative* hypotheses (H_1):

H_1 2: The addition of a rocker sole shoe to the treatment of CLBP will result in a significant reduction in pain (Numerical Rating Score) in patients with CLBP when compared to the addition of a flat sole shoe when assessed at six weeks, six months and one year.

H_1 3: For people reporting pain on standing or walking, there will be a better outcome for disability in people wearing rocker sole shoes when compared to people wearing flat sole shoes at six weeks, six months and one year.

5.3 Methods

5.3.1 Design

A multi-centre randomised, controlled trial was conducted with assessment of participants at baseline, six weeks, six months and twelve months. The chief investigator (C.I.) remained blind to participant group allocation for the duration of the data collection period.

5.3.2 Participant recruitment

Ethical Approval for the study was obtained from the Riverside Research Ethics Committee (REC reference number: 09/H0706/4) *(11.18, p262).* A total of 115 participants were recruited from the neuro-musculoskeletal physiotherapy department at the following locations:

- Balance Performance Physiotherapy, Clapham, London SW4
- Chelsea and Westminster Hospital, Chelsea, London SW10
- Kingston Hospital, Kingston, Surrey KT2
- St. George's Hospital, Tooting, London SW18
- Queen Mary's Hospital, Roehampton, London SW14

All patients referred from general practitioners and consultants for CLBP at the five participating physiotherapy sites were screened for appropriateness to participate (using the study screening sheet, *(11.19, p266*). The physiotherapist at each site responsible for triaging new referrals placed a purple sticker on those referrals that appeared appropriate for inclusion into the study. This aimed to increase the rate of recruitment by highlighting potential participants to the physiotherapists assessing them. Patients were deemed suitable for inclusion in the study if they met all of the inclusion criteria, and did not fulfil any of the exclusion criteria (Table 5.1). Patients fulfilling the inclusion criteria and interested in taking part in the research study were asked by their physiotherapist to read the Patient Information Sheet *(11.20, p267)* and informed that the C.I. would be in telephone contact in the following week to discuss the study in greater depth. During the telephone conversation with the C.I. the study screening questions were reassessed, and the study protocol described to the potential participant. If the potential participant provided verbal consent to take part in the research an appointment was arranged within the physiotherapy department at the referring site to gain written consent and to conduct the baseline assessment.

Table 5.1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Aged 18 to 65 years • More than 3 months of persistent or recurrent episodes of LBP • Lumbosacral pain with or without referral (of a non-radicular nature) • Pain of a mechanical nature (pain aggravated or eased by activity) • Willing to comply with the randomisation process • Able to fully communicate in English • Able to participate in an exercise group and perform exercises at home	• Constant pain • Non mechanical pain (pain that is not eased or aggravated by activity or posture) • Nerve root entrapment accompanied by neurological deficit • Neoplasms • Severe structural deformity/osteoporosis • Known spondylolysthesis/ spinal stenosis • Fracture of the spine within the past year • Inflammatory disease of the spine • Spinal infection • Severe cardiovascular/ metabolic disease • Pregnancy • Previous spinal surgery • Known Morton's Neuroma • Skin ulceration over the foot • Peripheral neuropathy with loss of sensation • History of falls • Surgery to the lower limb in the past 8 weeks • History of deep vein thrombosis (DVT) yet to be stabilised /yet to be advised to return to exercise by their medical practitioner • Unresolved legal issues regarding their back pain • Participants who have previously used rocker sole shoes

5.3.3 Outcome measures

The primary outcome measure was the Roland Morris Disability Questionnaire (assessing self-reported disability).The secondary outcome measures assessed in the main study are presented in Table 5.2. Justification for choice of main study outcome measures is presented in Chapter 4 *(4.3.4, p46).*

Table 5.2 Secondary outcome measures

Secondary outcome measures
• Numerical Rating Score for pain (self-reported pain) • EuroQol (EQ-5D-3L) health questionnaire (a measure of health related quality of life) • Patient Specific Functional Score (PSFS)(a questionnaire used to quantify activity limitation/measure functional outcome in patients) • Tampa Scale of Kinesiophobia (a questionnaire measuring fear of movement and fear of (re)injury during movements) • Hospital anxiety and depression score (a questionnaire measuring anxiety and depression) • Range of lumbar spine movement (flexion, extension, left and right side flexion) • Straight leg raise • Thoracic spine kyphosis angle • Hours study shoes worn per day

5.3.4 Consent and randomisation

Study participants were consented into the study by the C.I. *(11.8, p241)* and were assigned by block randomisation (blocks of four), into one of two groups:

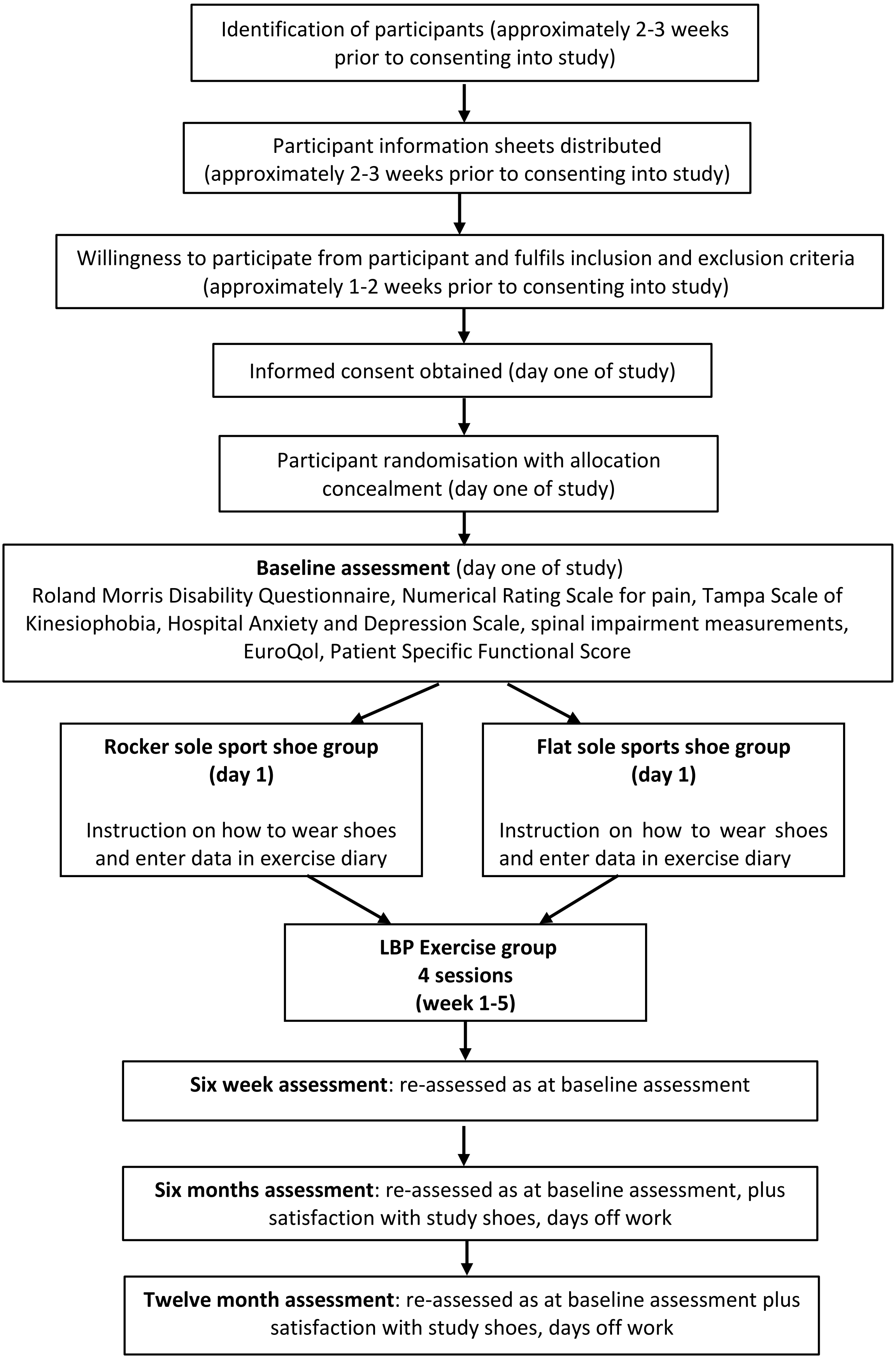
- Group 1: Participants received a pair of rocker sole sports shoes and attended four back exercise group sessions over four weeks
- Group 2: Participants received a pair of flat sole sports shoes and attended four back exercise group sessions over four weeks

The block randomisation protocol was chosen in order to ensure i). the numbers of participants in each group remained similar at all times, as demonstrated in the pilot study, and ii). that groups were not influenced by selection bias (by the participant or the investigator) which could lead to an overestimate or underestimate of differences between treatments (Altman and Bland, 1999). The number of possible combinations for a block size of four with two rocker sole shoe and two flat sole shoe allocations per block was calculated as six. Choosing to randomise with blocks of four ensured that the numbers in the two groups at any time would not differ by more than half the block length i.e. two participants at each site. It was deemed important to keep the block size small because if group size at each site did differ by two, it is possible that group differences may be as large as 10 participants across the study. A larger choice of block size increases the possibility of larger differences between groups. These blocks were written on pieces of paper by Dr Matt Morrissey (original PhD supervisor before he left King's College London), folded over, and then randomly selected to determine the order of group allocation for participants entering the study. Five separate randomisation sheets were produced in this manner, one for each site, with a total of 60 potential participant group allocations (15 separate blocks) per randomisation sheet. The block randomisation sheets were forwarded to the Primary Investigators (P.I.) at each referring site, and were kept on a password protected computer at each site. This prevented accidental release of allocation information to the C.I. A list of all P.I.s and co-researchers at each site can be found in *11.21 (p274).*

5.3.5 Outcome points

Participants were assessed at baseline, six weeks, six months and one year from the first assessment. The six week assessment aimed to detect combined change in outcome measures corresponding to completion of the back exercise class and early use of study footwear. The six month assessment aimed to detect outcome measure changes occurring following the prolonged use of study shoes. Primary outcome point occurred at one year from baseline to provide adequate follow-up time for such a chronic, recurrent and fluctuating condition. The one year assessment marked the end of each participant's involvement in the study. A flow chart of participant involvement in the study is presented in Figure 5.1.

Figure 5.1 Participant pathway



5.3.6 Format and standardisation of baseline assessment

The initial evaluation consisted of assessment of patient questionnaires, impairment measurements, instruction on completion of a diary sheet *(11.9, p243)* and the fitting of the allocated footwear accompanied by an education session on correct standing and walking technique for both footwear types *(11.22, p275).* In order to standardise this assessment between participants and between sites, a specific assessment order was adhered to:

1. Verbal review of study involvement with potential participant
2. Gaining of consent
3. Participant completed outcome measures in the following order: Roland Morris Disability questionnaire, Numerical rating score for pain, Hospital Anxiety and Depression score, EuroQol health questionnaire, Tampa Scale of Kinesiophobia, Patient Specific Functional Score
4. Impairment measures in the following order: thoracic spine kyphosis angle, range of lumbar spine flexion, extension, right and left side flexion, right and left straight leg raises
5. Instruction on completion of diary sheet
6. Fitting of study shoes, instruction on standing and walking in study shoes (co-researcher in absence of C.I.)

The roles of the P.I.s and co-researchers at each site included checking group randomisation allocation for each participant, fitting each participant with the appropriate study shoes and instructing them in the correct walking and standing technique whilst wearing the footwear. The C.I., blind to participant group allocation, was responsible for supervising each participant whilst outcome measure questionnaires were completed, recording the thoracic kyphosis angle and spinal impairment measurements (motion into flexion, extension, left and right side flexion, and left and right straight leg raise (SLR)), and instructing each participant on correct completion of the diary sheet. The methods used for assessing lumbar and thoracic movement have been demonstrated to be reliable by Lewis at al. (Lewis et al., 2005) and by the C.I. (van Blomestein et al., 2012) in a reliability study for this research project *(4.4, p53 and 11.13, p249). T*o summarise the methodology, patients stood barefoot in their normal posture, feet hip width apart and arms relaxed at their sides, whilst the C.I. took readings from the T1-2 spinous processes and the T12-L1 spinous processes using an inclinometer (Isomed, 975 Sandy Blvd., Portland, OR 97214) (Figure 5.2).

With their feet in the same position participants were then asked to lean forwards, then backwards, then to each side, until their pain started to present or worsen for each movement. Using a 'non-stretch' tape measure the distance between the participant's left middle fingertip and the floor directly below the left medial malleolus was recorded for the flexion and extension movements; for the side flexion movements the ipsilateral middle fingertip and the floor just behind the lateral malleoli were used as marker points for measurement recording. In order to assess SLR the inclinometer was placed on the tibial tuberosity, and the C.I. raised the participant's leg. Three readings for each movement were taken and the average used in the data analysis. Participants were asked to report when their symptoms of pain presented, or worsened, at which point movement was stopped and the inclinometer reading recorded. A Numerical Rating Score (NRS) for pain (from 0 to 10, where 0 = no pain, and 10 = worst imaginable pain) was requested from the participants at the point when each range of movement was recorded. Measurements were documented on the Participant Assessment Sheet *(11.23, p281).*

<u>Figure 5.2 Isomed inclinometer</u>

5.3.6.1 Observation of the assessment of participants.

Dr Matt Morrissey (original PhD supervisor before he left Kings College London) observed the C.I. during an initial participant assessment to ensure the procedure for gaining a participants consent was appropriate, and to verify that assessment of the participant was of a high standard.

5.3.7 Interventions

5.3.7.1 Footwear

Choice of study shoes

Masai Barefoot Technology Limited manufactures a large variety of rocker sole shoes. It was deemed important to select a single footwear model for the participants allocated to the rocker sole shoe group, that:

- appeared practical to wear throughout the year i.e. not a sandal model
- appeared to be of a colour practical to wear both in leisure and work time, to increase the likelihood that participants would wear the shoes for a minimum of two hours per day.
- was a unisex model, to ensure standardised footwear design between genders.
- displayed minimal branding logos on the shoe outer, sole and insole.

With these points in mind the 'Chapa' style shoe in 'caviar black' was selected. These shoes had a retail value of £179 per pair (Figure 5.3).

Selection criteria for the flat sole shoe were identical to the rocker sole shoe selection criteria, with the addition of:

- a sports trainer in design – the chosen rocker sole shoe was from the manufacturers 'sports trainer' range
- a model likely to be manufactured for the duration of the recruitment period of the trial, ensuring all participants in the flat sole shoe group would be allocated the same model of trainers.
- a shoe marketed to provide good shock absorption qualities (in an attempt to concur with the shock absorption reportedly offered by the rocker sole shoe).

- a neutral/ minimal support footwear type that would be suitable for the majority of participants.

The flat sole shoe chosen, fulfilling all these criteria was an ASICS ™ sports trainer, model 'Gel-1140' (Figure 5.3). This shoe had a 'GEL cushioning system' in the sole (suggested to improve shock absorption by dissipating vertical impact forces (ASICS, 2012)), and offered slight additional support to the midfoot when compared to a neutral trainer. From discussions with a specialist sports physiotherapist (Mr Graham Anderson, Balance Performance Physiotherapy, London, SW4) this shoe was deemed to be a high quality sports trainer suitable for a variety of foot types. These shoes had a retail value of £70.

<u>Figure 5.3 Study footwear</u>

(top: flat sole shoe; bottom: rocker sole shoe)

Unbranding of study shoes

Before a participant received their study shoes the shoes were unbranded with the aim that participants remain as blind as possible to their allocated shoe brand. This involved the C.I. removing or concealing company logos on the shoes by use of a scalpel, a black marker pen, or a piece of sand-paper as appropriate. The unbranded rocker sole and flat sole shoes are demonstrated in Figures 5.4 and Figure 5.5.

Figure 5.4 Unbranded rocker sole shoes

a). Unbranded shoe inner (right)

b). Unbranded shoe heel (left)

c). Unbranded shoe sole (left)

Figure 5.5 Unbranded flat sole shoes

Unbranded shoe tongue (left)

Training of co-researchers to fit study shoes, and instruct the participants in the correct study shoe walking technique

Co-researchers at each site were trained for approximately 30 minutes by the same representative from Masai Barefoot Technology (MBT) GB Ltd on the correct fitting and walking techniques for the rocker sole shoes. The C.I. was present at all five sites during these training sessions. Co-researchers were given a document for both the flat sole and rocker sole shoes describing the exact wording to be used when instructing participants on the correct walking style for each shoe type *(11.22, p275).* This was to ensure that co-researchers at each site relayed similar information to every study participant.

Allocation of shoes to study participants and education on correct standing and walking technique

Following completion of all outcome measures at the initial assessment the C.I. left the assessment area. A co-researcher then fitted the participant with their allocated shoe type in accordance with the randomisation sheet specific to each hospital and instructed them on correct standing and walking technique for their allocated shoes. The fitting session lasted approximately 30 minutes.

Participants were able to try on a variety of sizes in their allocated footwear to ensure the pair they received offered them the best fit. The C.I. ensured that prior to the assessment the appropriate sizes of shoe were available in each shoe type. This required there to be in stock the shoe size of the participant, a size above and a size below. If none of the available allocated shoes fitted the participant, the C.I. delivered the appropriate size in both shoe types (in order that the C.I. remained blind to shoe group allocation) to the P.I. at the earliest convenience and the participant returned to the department to be refitted. In order that the C.I. did not guess, through knowledge of the remaining shoes in stock, which shoe had been allocated, the P.I. or co-researcher would place a variety of footwear pairs in the C.I.'s shoe travel case (used for delivering footwear to each site). This case would then be taken back to the main footwear store (Chelsea and Westminster Hospital), whereby the P.I. at this site would again replace pairs in their store with those in the C.I.'s suitcase. This aimed to reduce the ability of the C.I. to determine, from remaining stock, which participant had been allocated to which footwear group at each site.

'Adaptation week' for footwear use

Baseline assessment and shoe fitting occurred approximately one week before participants started the low back pain exercise group. During this 'adaptation week' participants were given instruction to gradually increase the time study shoes were worn each day, initially wearing for only 15-30 minutes, progressing to a minimum wear of two hours per day (whilst standing and walking) by the start of their first exercise group. This 'pacing' procedure aimed to reduce the potential for the occurrence of other aches or pains secondary to the wearing-in process of a new pair of shoes.

5.3.7.2 Low back exercise group

Participants were asked to attend the back exercise group once a week for a period of four weeks (four back exercise classes in total). The back exercise group involved education, advice and a ten station exercise circuit. Each class was approximately one hour in duration. Study participants were informed to wear their study shoes during the low back exercise group.

Quality assurance and standardisation of exercise group between sites

In order to standardise this intervention the C.I. designed a back exercise class to be run at all sites. Exercises were chosen according to the latest research recommendations for management of CLBP (McGill, 2007; NICE, 2009), whilst considering the available space, equipment, and class duration time at each site. In developing the programme, the C.I. liaised closely with the back exercise group co-ordinators at each of the five sites, observing all current back exercise groups, in order to gain more knowledge on which group formats and which group diary scheduling times had higher patient recruitment and retention rates.

Format of low back exercise group

The finalised study exercise programme was composed of a five minute warm-up, ten exercises, of 90 seconds duration, each designed with three levels of progression, to accommodate each participant's ability (*11.24, p282)*, a five minute warm-down and a ten minute education/advice session. The exercises aimed to improve strength of large muscle groups and cardio-vascular fitness, in addition to specific trunk muscle exercises. The topics covered during the four education sessions were entitled 'Managing a flare up', 'Pain', 'Exercise' and 'Relaxation' *(11.25, p286)*. Classes were run with a maximum of ten participants and, site-dependent, one or two physiotherapists. This format, incorporating general exercise with education and advice and conducted under supervision, is a recommended best practice treatment approach for CLBP patients (Liddle et al., 2007; NICE, 2009).

Observation of exercise classes to ensure consistency and correct performance at study sites

The C.I. observed the back exercise group at all sites prior to the recruitment of participants into the study, and again once the last participant to enter the study had completed exercise group attendance. This assessed whether the standardisation of the exercise group protocol at all sites had been maintained over the duration of the study. The C.I. was unable to observe the exercise groups during the study recruitment period due to the likelihood of the presence of research participants wearing their study shoes, hence, removing the blinding of the C.I. to participant group allocation.

5.3.8 Six week assessment

The C.I. reassessed participants following the completion of the four week exercise programme. This assessment took place at approximately six weeks from baseline assessment. The assessment involved the same questionnaires and physical tests as performed at baseline. Participants were asked to hand in their completed diary sheets but asked to continue wearing their study shoes for a minimum of two hours each day.

5.3.9 Six month assessment

Participants were reassessed at six months (the same questionnaires and physical tests as performed in assessment one). All outcome measures assessed at baseline were completed. In addition participants were asked the following questions:

- On a scale of 0-7 where 0 represents totally unsatisfied and 7 represents extremely satisfied, how satisfied are you with the shoes you received?
- Over the last week, how many days did you wear your study shoes?
- Over the last week, on average, how many hours per day did you wear your shoes?
- Over the past six months have you had to take any days off work as a result of your back pain

Participants were asked to continue wearing their study shoes for a minimum of two hours a day until their final one year follow-up assessment.

5.3.10 One year assessment

The final assessment occurred at one year from baseline. This assessment replicated the six month assessment. At the end of the one year follow-up assessment participation in the research study ended. Participants were able to keep their study shoes if they so wished.

5.3.11 Sample size calculation

The minimal clinically important difference and the standard deviation from the mean of the primary outcome measure, the Roland Morris disability questionnaire, informed the study sample size. The smallest change likely to be clinically significant in the Roland Morris Disability Questionnaire (where scores can range from 0-24) may vary depending on the level of disability of the patients (Stratford et al., 1998). Stratford et al. (1998) suggested that the minimal clinically important difference in scores is one to two points in patients with little disability, seven to eight points for patients reporting high levels of disability, and five points in patients with unspecified disability levels. Patrick et al. (1995) suggest two to three points as the minimum clinically important difference for a 23 item version of the RMDQ (Jaeschke et al., 1989). Participants in the pilot study *(4.2, p33)* reported a mean baseline Roland Morris Disability score of 7.1, indicating mild to moderate disability in the study population. Therefore, a reduction in score of greater than or equal to four points on the Roland Morris Disability Questionnaire was determined to represent an improvement in this study (Maughan and Lewis, 2010). One purpose for conducting the pilot study was to inform the main study of an appropriate sample size. The standard deviation of mean Roland Morris Disability Questionnaire data from the pilot study (5 points on the RMDQ) was inputted into the sample size calculation (Sim and Wright, 2000) for the main study:

$$n \geq \frac{2\,(Za + Zb)^2\sigma^2}{\delta^2}$$

"where:

n is an adequate size for a random sample for each population

σ is the standard deviation for individual values in the population (5 points on the RMDQ)

δ reflects the difference in population means deemed important to detect (4 points on the RMDQ)

Za+Zb are standardised scores associated with the required significance level and power, respectively" (Sim and Wright, 2000).

Significance level	Za	Power	Zb	Za+Zb	$(Za+Zb)^2$
0.01	2.576	0.9	1.282	3.858	14.884

For a power of 0.9 and an alpha of 0.01 based on a standard deviation of five (standard deviation data collected from participants in the pilot study) and an ability to detect a four point change in the mean Roland Morris Disability Questionnaire scores between baseline and reassessment, the number of participants needed for each of the groups equalled 47. This was increased to 60 to allow for an anticipated 20% participant loss-to-follow up and missing data (Schulz and Grimes, 2002). Therefore, it was anticipated that approximately 120 participants would need to be recruited.

5.3.12 Adverse events

Adverse events were defined as an increase in pain or symptoms within one week of commencing an intervention (the 'adaptation week' for initial shoe wear, and a participants first week of attendance at the low back exercise group) that required general practitioner or casualty consultation as reported to the investigator (Hay et al., 2005).

5.3.13 Data analysis

Baseline data are presented in order that results may be compared with other trials and to judge the effectiveness of participant randomisation. Distributions were checked to see if normal distributions had been met, if this was not the case, non-parametric tests were performed. Independent t-tests for parametric data, were applied to determine differences between groups. When assumptions of normality were not met, and data were non-parametric, the Mann-Whitney test was performed.

The primary analysis was by intention-to-treat, including all eligible randomised participants who provided follow-up data. Mixed analysis of variance (ANOVA) tests were conducted with one within-subject factor (assessment time point) and one between group factor (shoe type) to compare the effectiveness of shoe type over the duration of the study (rocker sole shoes versus flat sole shoes). ANOVA utilised data from participants with complete data sets for all four time points (rocker sole shoe group n = 40, flat sole shoe group n = 43) unless otherwise stated. If differences were demonstrated between groups, post hoc tests were conducted with Bonferroni adjustment.

Although not significantly different, baseline mean disability was lower in the rocker sole shoe group than the flat sole shoe group. An ANCOVA takes into account differences between groups in specific variables which may influence outcomes (Field, 2009), such as baseline disability. Therefore, data was further analysed using an ANCOVA with baseline Roland Morris Disability Questionnaire score as a covariate. A further sensitivity analysis used 'expectation maximisation' to impute missing values.

A difference of greater than or equal to a four points change in RMDQ was taken to represent a clinical improvement in this study (Maughan and Lewis, 2010). Changes in RMDQ score between baseline and each reassessment were calculated. Participants were labelled as 'improved' if their RMDQ score reduced by 4 or more points, 'did not improve' if their score reduced by less than 4 points and did not increase by 4 points of more, and 'became worse' if their score increased by greater than 4 points. Differences between groups for numbers reporting minimal clinically important differences were assessed with Chi-squared (χ^2) test.

One pre-planned sub-group analysis was conducted. Rocker sole shoes influence body kinetics and kinematics, during standing and walking (New and Pearce, 2007; Nigg et al., 2006b; Romkes et al., 2006). Hence, it was supposed that the rocker sole shoe may be more likely to influence low back symptoms in those who reported difficulties in these activities. Data from participants reporting LBP aggravated by standing or walking activities on the Patient Specific Functional Scale at baseline were analysed with: mixed ANOVA utilising data from participants with complete data sets and; mixed ANOVA with missing number imputation, to determine whether shoe allocation influenced disability in this sub-group. An ANCOVA was not conducted on this sub-group due to the similarity of baseline disability between groups.

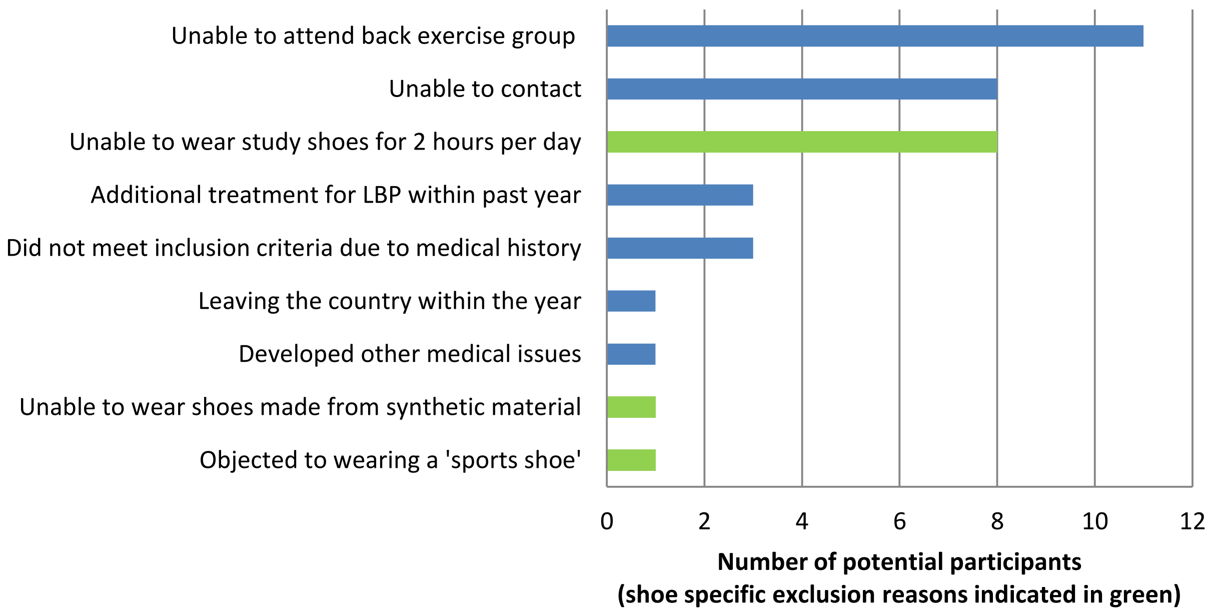
Data were analysed using IBM SPSS 20.0.0 (IBM, New York). Results are presented as means (standard deviations [SD]) unless otherwise stated.

5.4 Results

5.4.1 Participant recruitment

During the recruitment period (April 2009-November 2010) 152 patients were identified, by physiotherapists at the five referring sites for inclusion into the study. Following either a telephone conversation or a face-to-face meeting with the C.I., 37 of these potential participants were deemed ineligible to be recruited into the trial. Reasons for the exclusion of these potential participants are presented in Figure 5.6. One hundred and fifteen patients were consented into the study.

Figure 5.6 Reasons for exclusion of potential participants



5.4.2 Participant demographic characteristics

One hundred and fifteen participants were consented into the study between April 2009 and November 2010. Baseline study demographics and baseline outcome measures for the 115 participants are presented in Table 5.3 and Table 5.4 respectively. There were no differences between groups for demographic data or outcome measures, however, Roland Morris Disability Questionnaire and Quality of Life EQ-5D-3L scores tended to be greater (indicating greater disability and a better quality of life respectively) in the flat sole shoe group than the rocker sole shoe group.

Table 5.3 Participant demographic data

	Flat sole shoe group (n=58)	Rocker sole shoe group (n=57)	P - value
Gender: Male	19 (32.8)*	20 (35.1)*	0.79†
: Female	39 (67.2)*	37 (64.9)*	
Age [yrs]	43.0 (12.1)	43.1 (12.1)	0.98
Weight [kg]	75.7 (14.0)	74.3 (14.7)	0.38
Height [cm]	170.0 (7.4)	169.1 (9.8)	0.61
Body Mass Index [kgm^{-2}]	26.2 (4.59)	25.7 (4.73)	0.53
Time since first episode of LBP [years]	7.9 (9.0)	7.0 (7.9)	0.57

Summary measures represent means (SD) or *numbers (percentages). †Chi-square test otherwise independent t-test.

Table 5.4 Baseline outcome measures

Outcome measure	Flat sole shoe Group (n=58)	Rocker sole shoe group (n=57)	P - value
Disability score [0-24; 0=best]	9.2 (4.7)	7.8 (5.0)	0.13
Pain score [0-10; 0=best]	6.6 (2.0)	6.6 (1.7)	0.91
Quality of life (EQ-5D VAS) [0-100; 100=best]	67.8 (16.8)	62.7 (19.0)	0.13
Quality of life (EQ-5D) [-0.5 to 1.0; 1 = best]	0.68 (0.16)	0.62 (0.24)	0.10
Tampa Scale of Kinesiophobia [17-68; 17 = best]	38.4 (6.5)	38.4 (6.1)	0.64
Hospital Anxiety and Depression Scale: Anxiety component [0-21; 0=best]	7.7 (3.6)	7.5 (4.2)	0.33
Hospital Anxiety and Depression Scale: Depression component [0-21; 0=best]	5.2 (3.1)	4.8 (3.7)	0.22
Patient Specific Functional Scale [0-10; 10 = best]	4.5 (1.7)	4.3 (1.8)	0.46
Pain on standing or walking†	30 (51.7)*	29 (50.9)*	0.93**

Summary measures represent means (SD) or *numbers (percentages) **Chi square test, otherwise independent t-test. †as reported on the Patient Specific Functional Scale.

5.4.3 Participant retention and attrition

At six weeks 100 (87%) participants were reassessed; at six months 92 (80%) participants were reassessed; and at 12 months 93 (81%) participants were reassessed. Retention at 12 months tended to be lower in the rocker sole shoe group [44/58 (77.2%)] than the flat sole shoe group [49/57 (84.5%)] but not significantly (p = 0.32). Participant attrition and retention during the study are presented in a CONSORT diagram (Figure 5.7).

Figure 5.7 Flow of participants through trial

Assessed for eligibility by C.I. (n =152)

Excluded (n= 37)
29 did not meet inclusion criteria
8 unable to contact

Consented and randomised into the trial (n=115)

Flat sole shoe group
Total randomised (n=58)
58 (100%) started allocated intervention

6 week follow up
Total completing data collection (n=50)
- Completed intervention (n=50)
- Did not complete intervention (n=0)

Total lost to follow-up (n=8)
- unable to attend assessment: CW18, SG10
- unable to contact: CW29, CW36, KH3, SG6, SG19
- withdrew due to time commitments:CW48

6 month follow up
Total completing data collection (n= 47)
- Completed intervention (n=41)
- Did not complete intervention (n=6)

Total lost to follow-up (n=11)
- unable to attend assessment: CW10, CW39, QM3, QM7
- unable to contact: CW29, CW36, CW52, KH3, SG6, SG19
- withdrew due to time commitments:CW48

12 month follow up
Total completing data collection (n= 49)
- Completed intervention (n=42)
- Did not complete intervention (n=7)

Total lost to follow-up (n=9)
- Unable to contact: CW16, CW29, CW30, CW36, CW52, KH3, SG6, SG19
- withdrew due to time commitments: CW48

Total included in final analysis
(n= 49)
% dropout = 15.5%

Rocker sole shoe group
Total randomised (n=57)
57 (100%) started allocated intervention

6 week follow up
Total completing data collection (n=50)
- Completed intervention (n=49)
- Did not complete intervention (n=1)

Total lost to follow-up: (n=7)
- unable to attend assessment: CW53
- unable to contact: CW4, CW35, BP8, SG9
- withdrew due to blister from shoe wear: CW47
- withdrew due to fear of blisters (diabetic): QM11

6 month follow up
Total completing data collection (n=45)
- Completed intervention (n=38)
- Did not complete intervention (n=7)

Total lost to follow-up (n=12)
- unable to attend assessment: CW31, CW34, BP6
- unable to contact: CW4, CW15, CW19, CW35, BP8, SG1, SG9
- withdrew due to blister from shoe wear: CW47
- withdrew due to fear of blisters (diabetic): QM11

12 month follow up
Total completing data collection (n=44)
- Completed intervention (n=32)
- Did not complete intervention (n=12)

Total lost to follow-up (n=13)
- unable to contact: CW4, CW15, CW19, CW25, CW26, CW35, BP8, SG1, SG3, SG8, SG9
- withdrew due to blister from shoe wear: CW47
- withdrew due to fear of blisters (diabetic): QM11

Total included in final analysis
(n= 44)
% dropout = 22.8%

Participant identification codes are reported as initials of the referring site followed by a number identifying the 'nth' participant entering the trial at that site

5.4.4 Baseline characteristics of participants completing and participants not completing the trial

Twenty two (19%) participants did not provide primary outcome data (Roland Morris Disability Questionnaire) at the final assessment (twelve months from baseline). Baseline characteristics of participants completing and not-completing are presented in Table 5.5. There were no differences in baseline characteristics between participants that completed the trial and participants that did not. However, participants completing the trial tended to be older than those not completing the trial (44.0 (12.0) years and 39.2 (11.8) years respectively) and tended to report a longer duration of LBP than those not completing the trial (7.9 (9.0) years and 5.5 (5.0) years respectively). A greater proportion of those who did not complete the trial had been allocated to the rocker sole shoe group. Baseline fear of movement, anxiety and depression scores tended to be higher in participants that did not complete the trial compared to those who did.

5.4.5 Primary outcome: Roland Morris Disability Questionnaire

5.4.5.1 Comparison of change in disability between groups

Primary analysis

For the primary outcome, both groups demonstrated reductions in disability at each time point when compared to baseline ($F(2.21,92.62) = 21.63$, $p < 0.01$, $\eta^2 = 0.34$ for the flat sole shoe group and $F(2.46, 96.11) = 11.49$, $p < 0.01$, $\eta^2 = 0.23$) for the rocker sole shoe group) (Table 5.6, Figure 5.8). There were no differences between groups for change in disability at the four reassessment points ($F(2.39,193.21) = 1.56$, $p = 0.21$, $\eta^2 = 0.21$) indicating that change in disability was unaffected by the type of shoe worn in this study.

Following removal of two outliers highlighted from box plots of RMDQ baseline scores (one participant from the flat sole shoe group with RMDQ of 22 and one participant from the rocker sole shoe group with a RMDQ score of 23) a similar non-significant outcome was observed ($F(3,2.39) = 1.56$, $p = 0.21$, $\eta^2 = 0.02$). The removed outliers were replaced, and included in all further analysis of study data.

Table 5.5 Baseline characteristics of participants that did and did not complete the trial

	Participants completing trial (n=93)	Participants not completing trial (n=22)	P - value
Rocker sole group allocation	44/93 (47.3%)	13/22 (59.1%)	0.32
Female	61/93 (65.6%)	15/22 (68.2%)	0.82
Age	44.0 (12.0)	39.2 (11.8)	0.10
Time since first episode of LBP [years]	7.9 (9.0)	5.5 (5.0)	0.09
Roland Morris Disability Questionnaire [0-24; 0=best]	8.5 (4.9)	8.5 (5.0)	0.94
Numerical rating score for Pain [0-10; 0=best]	6.7 (1.8)	6.1 (2.1)	0.19
VAS for Quality of life EQ-5D-3L [0-100; 100=best]	66.6 (16.9)	59.8 (21.5)	0.11
Quality of life EQ-5D-3L [-0.5 to 1.0; 1 = best]	0.65 (0.21)	0.65 (0.19)	0.95
Tampa Scale of Kinesiophobia [17-68; 17 = best]	38.0 (6.)	40.0 (6.6)	0.17
Hospital Anxiety and Depression Scale: Anxiety component [0-21; 0=best]	7.4 (4.0)	8.8 (3.1)	0.11
Hospital Anxiety and Depression Scale: Depression component [0-21; 0=best]	4.9 (3.4)	5.7 (3.3)	0.28
Patient Specific Functional Scale [0-10; 10 = best]	4.3 (1.7)	4.8 (2.0)	0.27

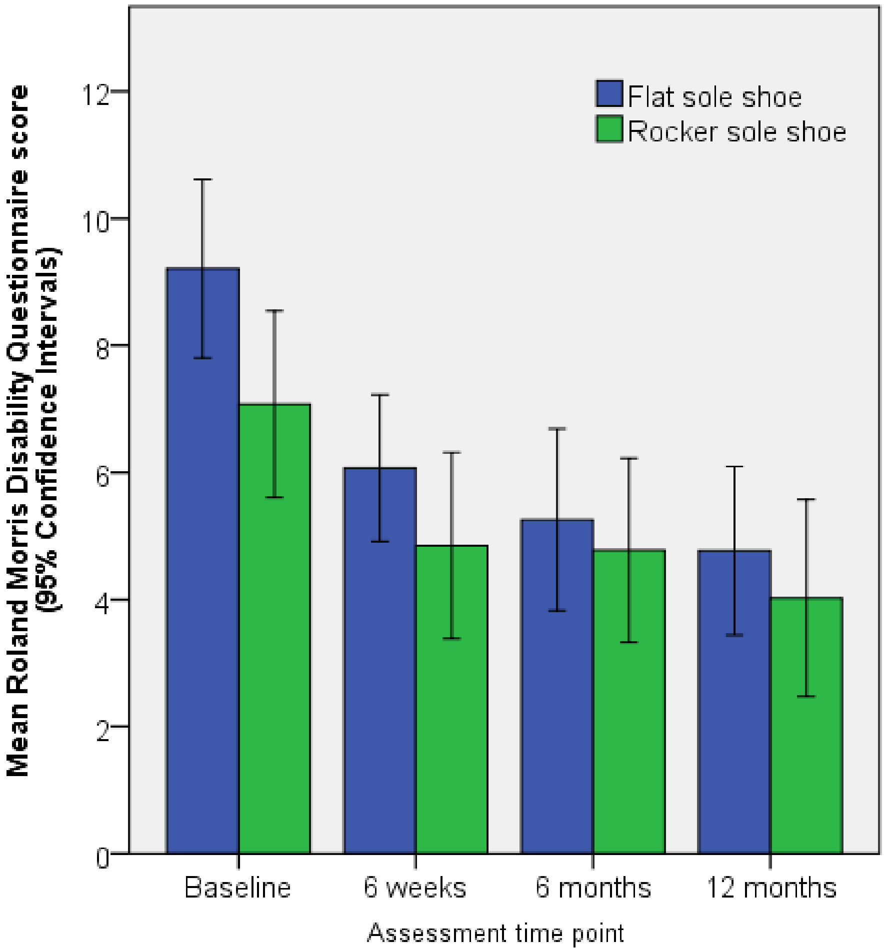
Summary measures represent means (SD) or *numbers (percentages)

Table 5.6 Roland Morris Disability Questionnaire score at each assessment

Outcome measure	Assessment point	Intervention: Flat sole shoe (n=43)	Intervention: Rocker sole shoe (n=40)
Roland Morris Disability Questionnaire [0-24; 0 = best]	Baseline	9.2 (7.8-10.6)	7.1 (5.6-8.5)
	6 weeks	6.1 (4.9-7.2)*	4.9 (3.4-6.3)*
	6 months	5.3 (3.8-6.7)*	4.8 (3.3-6.2)*
	12 months	4.8 (3.4-6.1)*	4.0 (2.5-5.6)*

Summary measures are Means (95% Confidence Intervals).* represents a significant (p<0.01, mixed ANOVA) within group score change when compared to baseline.

Figure 5.8 Roland Morris Disability Questionnaire score at each assessment



Sensitivity analyses

Although not significantly different, baseline mean disability was lower in the rocker sole shoe group than the flat sole shoe group by 1.4 points (and by 2.1 points when the mean is calculated using only data from the complete data sets utilised when calculating an ANOVA). Therefore, data was further analysed using an ANCOVA with baseline Roland Morris Disability Questionnaire score as a covariate. When taking into account the effect of baseline score, differences between groups for changes in Roland Morris Disability Questionnaire score between groups at reassessment remained non-significant ($F(1.76, 140.55) = 0.51$, $p = 0.58$, $\eta^2 = 0.006$).

There were no differences in disability between groups at reassessment following missing number imputation (using 'expectation maximisation') ($F(2.39,270.20) = 1.98$, $p = 0.13$, $\eta^2 = 0.02$) (Table 5.7).

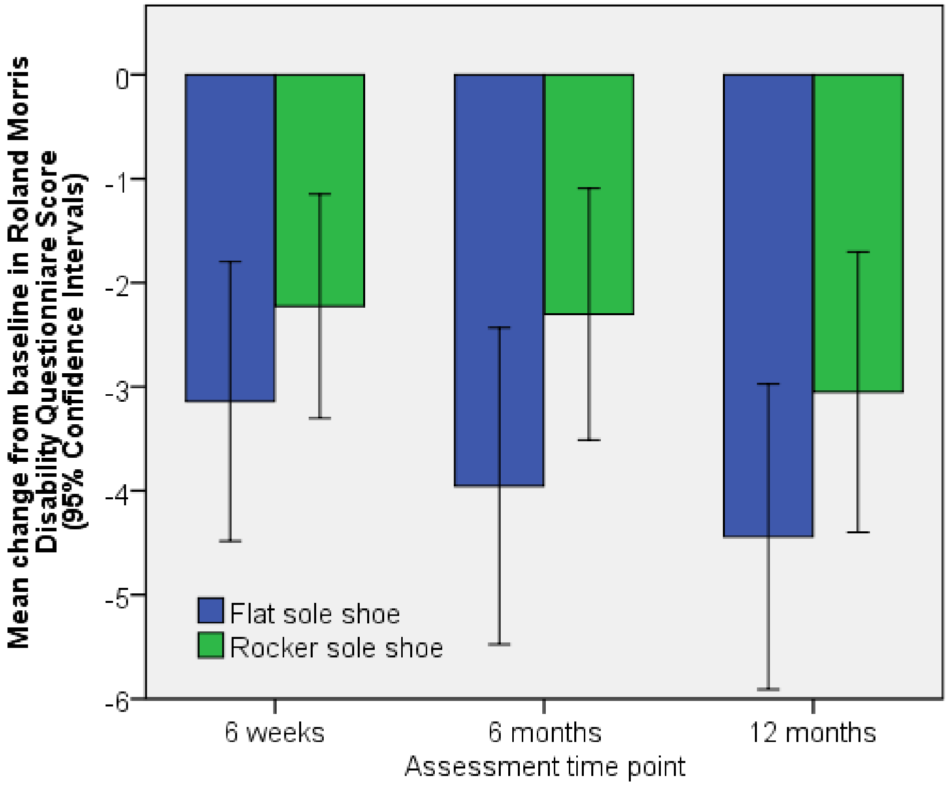
Table 5.7 Roland Morris Disability Questionnaire scores imputing missing values using expectation maximisation

Outcome measure	Assessment point	Intervention: Flat sole shoe (n=58)	Intervention: Rocker sole shoe (n=57)
Roland Morris Disability Questionnaire (0-24; 0 = best)	Baseline	9.2 (8.0-10.5)	7.8 (6.6-9.1)
	6 weeks	6.3 (5.1-7.4)	5.7 (4.5-6.9)
	6 months	5.4 (4.2-6.6)	5.4 (4.2-6.6)
	12 months	4.9 (3.6-6.1)	4.8 (3.5-6.0)

Summary measures are Means (95% Confidence Intervals)

Although not significant, there was a trend for reductions in disability at one year to be greater for the flat sole shoe group (-4.4 points, 95% confidence interval -5.8 to -3.1) than the rocker sole shoe group (-3.1 points, 95% confidence interval -4.5 to -1.6) (Figure 5.9).

Figure 5.9 Change in disability from baseline (negative value represents improvement in disability)



5.4.5.2 Participants achieving clinically important change in disability

At six weeks, 16/50 (32%) of the participants in the rocker sole group and 18/50 (36%) of the participants in the flat sole shoe group showed a clinically important improvement in perceived disability (a four point or greater reduction in the Roland Morris Disability Questionnaire) and 2/50 (4%) and 1/50 (2%) respectively reported a minimal clinically important deterioration (a four point or greater increase in the Roland Morris Disability Questionnaire score). These differences were not significantly different between the two footwear groups (χ^2 (1) = 0.18, p = 0.67 for clinically important improvement, and χ^2 (1) = 0.34, p = 0.56 for clinically important deterioration).

At six months, 13/45 (31%) of the rocker sole shoe group and 25/47 (53%) of the flat sole shoe group reported a minimal clinically important improvement (χ^2 (1) = 4.60, p = 0.03), indicating a greater proportion of participants allocated to wear flat sole shoes improved at six months when compared to those allocated to the rocker sole shoe group. At six months, 2/45 (4%) of those in the rocker sole shoe group and 2/47 (4%) in the flat sole shoe group reported a minimal clinically important deterioration in disability (χ^2 (1) < 0.01, p = 0.97).

At 12 months, 18/44 (41%) of the rocker sole shoe group and 26/49 (53%) of the flat sole shoe group demonstrated a minimal clinically important improvement, and 3/44 (7%) and 0/49 (0%) respectively reported a minimal clinically important deterioration regarding disability. These differences were not significant (χ^2 (1) = 1.37, p = 0.24 for clinically important improvement, and χ^2 (1) = 3.45, p = 0.06 for clinically important deterioration).

5.4.5.3 Comparison of disability scores for participants reporting pain aggravated by standing or walking

Baseline variables for the sub-group of participants reporting pain on standing or walking at baseline are presented in Table 5.8. There were no significant differences between shoe groups.

Table 5.8 Baseline data for those reporting pain on standing and walking

		Flat Sole Shoe (n=30)	Rocker Sole Shoe (n=29)	P - value
Demographic data	Gender: Male	9 (30.0)*	11 (37.9)*	0.52
	: Female	21 (70.0)*	18 (62.1)*	
	Age [years]	44.2 (11.9)	43.8 (12.4)	0.88
	Body Mass Index [kgm^{-2}]	26.9 (5.4)	26.17 (5.3)	0.62
	Time since first episode of LBP [years]	7.4 (7.1)	9.2 (9.5)	0.41
Outcome measures	Roland Morris Disability questionnaire	8.7 (4.8)	8.8 (5.8)	0.95
	Numerical rating score for pain	6.6 (1.9)	6.6 (1.9)	0.94

Summary measures represent means (SD) or *numbers (percentages)

Primary analysis

There were no between group differences in change in disability at reassessment within the sub-group of participants reporting pain on standing or walking (using the 43 complete data sets) (Table 5.9)($F(2.32, 95.22) = 2.35$, $p = 0.09$, $\eta^2 = 0.05$), however, there was a tendency for the flat sole shoe sub-group to demonstrate greater reductions in disability. The flat sole shoe sub-group demonstrated significant within group reductions in disability at all time points when compared to baseline ($F(1.97,43.34)=13.37$, $p < 0.01$, $\eta^2 = 0.38$) (Table 5.9).

Table 5.9 Disability of participants reporting pain on standing and walking

Outcome measure	Assessment point	Intervention	
		Flat sole shoe group (n=23)	Rocker sole shoe group (n=20)
Roland Morris Disability Questionnaire [0-24; 0 = best]	Baseline	8.2 (6.3–10.2)	7.3 (5.2-9.4)
	6 weeks	4.9 (3.2-6.6)*	6.4 (4.5-8.2)
	6 months	4.6 (2.7-6.5)*	5.6 (3.6-7.6)
	12 months	3.9 (1.8-6.0)*	5.6 (3.3-7.8)

Summary measures are Means (95% Confidence Intervals).* represents a significant ($p<0.01$) within group score change when compared to baseline.

Sensitivity analysis

Following missing value imputation, there was a significant difference in reduction in disability between the two shoe sub-groups at reassessment points ($F(2.24, 127.64) = 2.97$, $p = 0.046$, $\eta^2 = 0.05$). Participants in the flat sole shoe group showed a greater improvement in disability than participants in the rocker sole shoe group at six weeks ($p = 0.02$) and at twelve months ($p = 0.04$) when compared to baseline disability. At twelve months, participants in the flat sole shoe group demonstrated a reduction in Roland Morris Disability Questionnaire score of -4.4 (-6.0 to -2.8) and those in the rocker sole shoe group a reduction in score of -2.0 (-3.6 to -0.4) (Table 5.10, Figure 5.10).

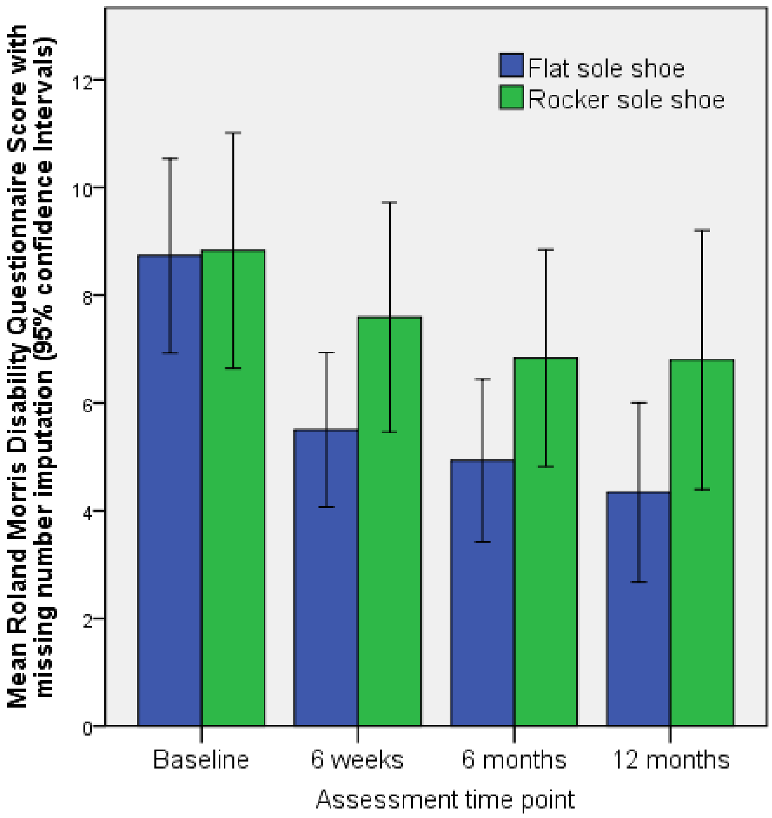
Table 5.10 Disability for sub-group of participants reporting baseline pain on standing or walking (with missing number imputation)

Outcome measure	Assessment point	Intervention: Flat sole shoe group (n=30)	Intervention: Rocker sole shoe group (n=29)
Roland Morris Disability Questionnaire [0-24; 0 = best]	Baseline	8.7 (6.8-10.7)	8.8 (6.9-10.8)
	6 weeks	5.5 (3.8-7.3)	7.6 (5.8-9.4)
	6 months	4.9 (3.2-6.7)	6.8 (5.1-8.6)
	12 months	4.3 (2.4-6.3)	6.8 (4.8-8.8)

Summary measures are Means (95% Confidence Intervals).

Figure 5.10 demonstrates disability at each assessment point for the sub-group of participants in each shoe group reporting baseline pain on standing or walking (with missing number imputation).

Figure 5.10 Disability for sub-group of participants reporting baseline pain when standing or walking (with missing number imputation)



(Reduction in score represents reduction in disability)

5.4.6 Secondary outcome measures

5.4.6.1 Pain intensity

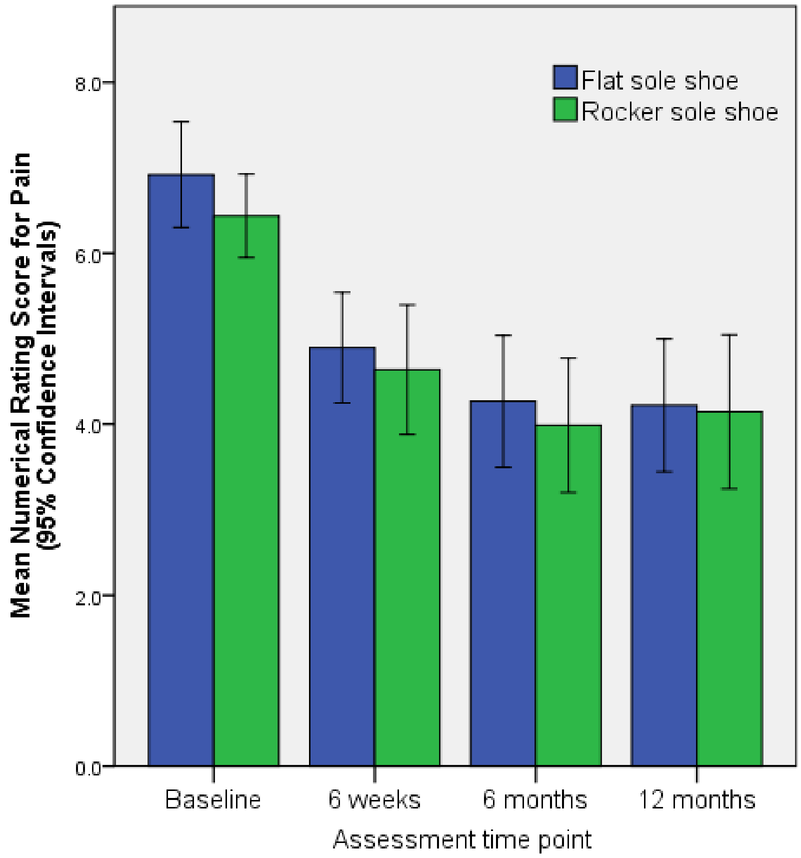
Both shoe groups demonstrated reductions in pain at each time point when compared to baseline (flat sole shoe group: $F(3,126) = 23.72$, $p > 0.01$, $\eta^2 = 0.36$; rocker sole shoe group $F(3, 117) = 13.43$, $p > 0.01$, $\eta^2 = 0.26$) (Table 5.11 and Figure 5.11). There were no between group differences in pain reduction over the four time points ($F(3, 243) = 0.17$, $p = 0.92$, $\eta^2 < 0.01$) indicating that the reduction in pain was unaffected by the type of shoe worn.

Table 5.11 Pain intensity: Numerical rating score

Outcome measure	Assessment point	Intervention: Flat sole shoe (n=43)	Intervention: Rocker sole shoe (n=40)
Numerical rating score for pain [0-10; 0 = best]	Baseline	6.9 (6.3-7.5)	6.4 (6.0-6.9)
	6 weeks	4.9 (4.3-5.5)*	4.6 (3.9-5.4)*
	6 months	4.3 (3.5-5.0)*	4.0 (3.2-4.8)*
	12 months	4.2 (3.4-5.0)*	4.2 (3.2-5.1)*

Summary measures are means (95% Confidence Intervals). * represents a significant (p<0.01) within group score change when compared to baseline.

Figure 5.11 Numerical rating scores for pain



5.4.6.2 Patient Specific Functional Score

Both groups demonstrated improvements in function at each time point when compared to baseline (flat sole shoe group: $F(2.12, 84.75) = 33.68$, $p <0.01$, $\eta^2 = 0.46$; rocker sole shoe group: $F(2.37, 90.00) = 23.96$, $p < 0.01$, $\eta^2 = 0.39$) (Table 5.12, Figure 5.12).

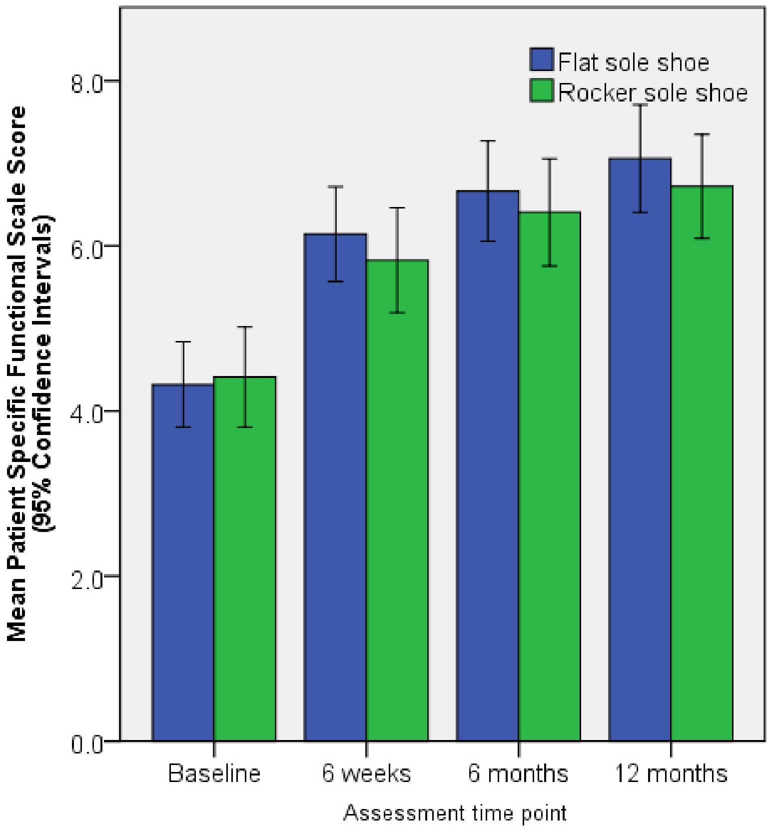
There were no between group differences in change in functional improvement over the four time points ($F(2.35, 183.29) = 0.46$, $p = 0.67$, $\eta^2 <0.01$) indicating that functional improvement was unaffected by the type of shoe worn.

Table 5.12 Patient Specific Functional Score

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Patient Specific Functional Scores [0-10; 10 = best]	Baseline	4.3 (3.8-4.8)	4.4 (3.8-5.0)
	6 weeks	6.1 (5.6-6.7)*	5.8 (5.2-6.5)*
	6 months	6.7 (6.1-7.3)*	6.4 (5.8-7.1)*
	12 months	7.1 (6.4-7.7)*	6.7 (6.1-7.4)*

Summary measures are means (95% Confidence Intervals). * represents a significant (p<0.05) within group score change when compared to baseline.

Figure 5.12 Patient Specific Functional Score



(Increase in score represents improvement in function)

5.4.6.3 Health related quality of life (EQ-5D-3L)

There was no change in health related quality of life in the rocker sole shoe group over the four time points ($F(2.38,83.26)=2.80$, $p=0.06$, $\eta^2=0.07$). The flat sole shoe group demonstrated an improvement in quality of life over the four time points ($F(2,23,88.99)= 3.47$, $p=0.03$, $\eta^2=0.08$); post hoc tests demonstrated an improvement in health related quality of life at 12 months compared to baseline ($p = 0.02$) (Table 5.13).

There were no between group differences for change in health related quality of life over the four time points ($F(3, 225) = 1.10$ $p = 0.35$, $\eta^2 = 0.01$) indicating that health related quality of life was unaffected by the type of shoe worn in this study.

Table 5.13 Health related quality of life

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Quality of life EQ -5D [-0.5-1; 1 = best]	Baseline	0.68 (0.64-0.72)	0.62 (0.55-0.68)
	6 weeks	0.74 (0.69-0.78)	0.63 (0.55-0.72)
	6 months	0.71 (0.66-0.76)	0.66 (0.66-0.73)
	12 months	0.76 (0.73-0.80)*	0.70 (0.62-0.79)

Summary measures are Means (95% Confidence Intervals). * represents a significant ($p<0.05$) within group score change when compared to baseline.

5.4.6.4 Health related quality of life (EQ-5D-3L) visual analogue score

Neither shoe group demonstrated change in health related quality of life over the four time points ($F(3,105)=1.79$, $p=0.15$, $\eta^2= 0.05$, and $F(3,130)=1,37$, $p=0.25$, $\eta^2= 0.03$ respectively) (Table 5.14).

There were no between group differences for change in visual analogue score for health related quality of life over the four time points ($F(3, 225) = 0.18$ $p = 0.91$, $\eta^2 <0.01$), indicating that the visual analogue score for health related quality of life was unaffected by the type of shoe worn.

Table 5.14 Visual analogue score for health related quality of life

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Visual analogue score for health related quality of Life (EQ-5D-3L) [0-100; 100 = best]	Baseline	70.0 (65.6-74.5)	64.4 (58.2-70.5)
	6 weeks	72.1 (67.1-77.0)	69.1 (62.5-75.8)
	6 months	72.0 (66.4-77.6)	66.9 (60.7-73.1)
	12 months	75.6 (71.0-80.3)	70.5 (63.3-77.6)

Summary measures are Means (95% Confidence Intervals).

5.4.6.5 Tampa Scale of Kinesiophobia

There was no change in self-reported fear of movement for the rocker sole shoe group over the four time points ($F(2.40, 83.85) = 1.69$, $p = 0.19$, $\eta^2 = 0.05$). The flat sole shoe group demonstrated improvement between the four time points ($F(2.47,98.95) = 3.36$, $p = 0.03$, $\eta^2 = 0.08$), however, post hoc tests did not show a difference between individual assessment points ($p > 0.05$) (Table 5.15).

There were no between group differences for change in self-reported fear of movement over the four time points ($F(2.57, 192.76) = 0.75$ $p = 0.51$, $\eta^2 = 0.01$, indicating that self-reported fear of movement was unaffected by the type of shoe worn.

Table 5.15 Tampa Scale of Kinesiophobia

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Tampa Scale of Kinesiophobia [17-68; 68 = best]	Baseline	37.9 (36.0-39.8)	36.2 (34.4-37.9)
	6 weeks	36.8 (34.9-38.6)	34.7 (32.5-36.9)
	6 months	37.1 (34.8-39.4)	34.7 (32.1-37.3)
	12 months	34.7 (32.0-37.4)	34.3 (31.8-36.7)

Summary measures are Means (95% Confidence Intervals).

5.4.6.6 Hospital Anxiety and Depression Scale: anxiety component

There was no difference in anxiety between time points in the rocker sole shoe group ($F(1.82,63.70) = 1.32$, $p = 0.27$, $\eta^2 = 0.04$). Anxiety scores in the flat sole shoe group differed between the four time points ($F(3, 120) = 3.73$, $p = 0.01$, $\eta^2 = 0.09$) with a reduction in anxiety at 6 weeks compared to baseline ($p = 0.02$) (Table 5.16).

There were no between group differences in change in anxiety over the four time points ($F(2.31, 173.36)=1.84$, $p=0.16$, $\eta^2=0.02$) indicating that self-reported anxiety was unaffected by the type of shoe worn.

Table 5.16 Hospital Anxiety and Depression Scale: anxiety component

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Hospital Anxiety and Depression Scale : Anxiety component [0-21; 21 = best]	Baseline	7.3 (6.2-8.4)	6.9 (5.4-8.4)
	6 weeks	6.1 (5.1-7.1)*	7.4 (5.7-9.0)
	6 months	6.9 (5.8-7.9)	7.2 (5.4-9.0)
	12 months	6.0 (4.9-7.1)	6.3 (4.7-8.0)

Summary measures are Means (95% Confidence Intervals).* represents a significant ($p<0.05$) within group score change when compared to baseline.

5.4.6.7 Hospital Anxiety and Depression scale: depression component

There was no change in self-reported depression in the rocker sole shoe group over the four time points ($F(3,105) = 0.08$, $p = 0.95$, $= \eta^2 <0.01$). Depression in the flat sole shoe group differed between the four time points ($F(2.40, 95.92) = 3.87$, $p = 0.02$, $\eta^2 = 0.09$) with a reduction in depression at six weeks compared to baseline ($p = 0.03$) (Table 5.17).

There were no between group differences for change in depression over the four time points ($F(2.60, 194.88) = 1.60$, $p = 0.20$, $\eta^2 = 0.02$) indicating that self-reported depression was unaffected by the type of shoe worn.

Table 5.17 Hospital Anxiety and Depression Scale: depression component

Outcome measure	Assessment point	Intervention	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Hospital Anxiety and Depression Scale : Depression component (0-21; 21 = best)	Baseline	4.7 (3.8-5.7)	4.3 (3.0-5.7)
	6 weeks	3.2 (2.3-4.2)*	4.1 (2.6-5.7)
	6 months	4.0 (3.1-5.0)	4.2 (2.4-6.0)
	12 months	3.5 (2.7-4.4)	4.3 (2.7-5.9)

Summary measures are Means (95% Confidence Intervals).* represents a significant ($p<0.05$) within group score change when compared to baseline.

5.4.6.8 Spinal impairment measures

Although a small number of within group changes in spinal impairment measures were demonstrated (flat sole shoe group: increase in spinal extension at six months, increase in left and right straight leg raise at six months and twelve months compared to baseline; rocker sole shoe group: increase in right spinal side flexion at twelve months and increase in right straight leg raise at six months) (Table 5.18), there were no between group differences over the four time points for change in range of:

- Spinal flexion ($F(2.67, 189.75) = 0.46$, $p = 0.69$, $\eta^2 <0.01$)
- Spinal extension ($F(1.62, 115.33) = 0.10$, $p = 0.86$, $\eta^2 <0.01$)
- Spinal left or right side flexions ($F(2.32, 164.53) = 0.11$, $p = 0.92$, $\eta^2 <0.01$, and $F(3, 213) = 1.68$, $p = 0.17$, $\eta^2 =0.02$ respectively)
- Left or right straight leg raise ($F(3, 213) = 1.70$, $p = 0.17$, $\eta^2 = 0.02$, and $F(2.43, 172.53) = 0.77$, $p = 0.49$, $\eta^2 =0.01$ respectively)
- Thoracic spine kyphosis angle ($F(3, 213) = 1.34$, $p = 0.26$, $\eta^2 =0.02$)

This indicated that spinal impairment measures were unaffected by the type of shoe worn.

Table 5.18 Spinal impairment measures

Outcome measure	Assessment point	Intervention group	
		Flat sole shoe (n=43)	Rocker sole shoe (n=40)
Spinal flexion [cm]	Baseline	20.9 (15.8-25.9)	19.1 (13.5-24.8)
	6 weeks	20.7 (15.2-26.1)	19.0 (13.8-24.2)
	6 months	17.8 (12.9-22.8)	18.5 (13.7-23.2)
	12 months	17.8 (13.0-22.6)	17.1 (11.9-22.3)
Spinal extension [cm]	Baseline	62.9 (61.5-64.2)	62.2 (60.6-63.8)
	6 weeks	61.9 (60.5-63.3)	61.2 (59.7-62.7)
	6 months	61.3 (59.8-62.8)*	60.3 (56.6-64.0)
	12 months	61.8 (60.1-63.5)	61.5 (59.8-63.2)
Spinal left side flexion [cm]	Baseline	48.4 (46.6-50.2)	48.2 (46.4-50.1)
	6 weeks	48.3 (46.7-49.9)	48.3 (46.0-50.6)
	6 months	47.2 (45.7-48.7)	47.3 (45.5-49.1)
	12 months	46.7 (45.0-48.5)	47.1 (45.3-49.0)
Spinal right side flexion [cm]	Baseline	46.9 (44.8-49.0)	48.4 (46.8-50.1)
	6 weeks	47.1 (45.4-48.7)	47.1 (45.5-48.7)
	6 months	46.3 (44.7-47.8)	47.4 (45.7-49.1)
	12 months	46.8 (45.2-48.5)	46.9 (45.3-48.5)*
Left straight leg raise [degrees]	Baseline	71.9 (66.8-77.0)	78.8 (73.2-84.5)
	6 weeks	78.1 (73.2-82.9)	82.4 (75.6-89.1)
	6 months	80.8 (76.0-85.6)*	81.4 (75.1-87.6)
	12 months	78.4 (74.3-82.4)*	82.1 (76.1-88.0)
Right straight leg raise [degrees]	Baseline	68.6 (62.3-74.9)	75.6 (68.8-82.4)
	6 weeks	75.5 (70.8-80.2)	78.8 (72.9-84.7)
	6 months	78.3 (73.3-83.2)*	81.4 (76.0-86.9)*
	12 months	76.9 (72.3-81.6)*	80.4 (74.8-86.0)
Thoracic kyphosis angle [degrees]	Baseline	40.7 (37.8-43.6)	42.3 (38.8-45.9)
	6 weeks	39.2 (36.1-42.3)	40.5 (37.5-43.6)
	6 months	40.3 (37.6-43.1)	40.0 (36.6-43.4)
	12 months	42.8 (40.3-45.3)	41.3 (38.4-44.3)

Summary measures are Means (95% Confidence Intervals).* represents a significant ($p<0.05$) within group score change when compared to baseline (repeated measures ANOVA).

5.4.6.9 Time off work

For those in paid employment, there was no difference in the average number of days off work, resulting from low back pain, between the footwear groups from baseline to six months (U = 479.0, z = -0.77, p = 0.44) or from six months to twelve months (U= 505.5, z = -0.12, p = 0.91) (Table 5.19).

Table 5.19 Time taken off paid employment due to low back symptoms

Assessment point		Intervention	
		Flat sole shoe	Rocker sole shoe
Baseline to 6 months	Participants taking time off work	5/32 (15.6%)*	3/32 (9.4%)*
	Average days off work/participant	1.7 (6.5)	0.5 (1.6)
6 months to 12 months	Participants taking time off work	3/34 (8.8%)*	3/30 (10.0%)*
	Average days off work/participant	1.5 (6.2)	0.7 (2.8)

Summary measures represent means (SD) or *numbers (percentages)

5.4.6.10 Adherence to shoe use protocol.

There were no differences between groups in reported adherence to the shoe use protocol (to wear study shoes for two hours or greater each day) at the three reassessment points. At six weeks, there was a 52.4 % reported adherence to the shoe use protocol for the flat sole shoe group and a 60.0 % reported adherence for the rocker sole shoe group (χ^2 (1) = 0.48, p = 0.49). At six months, there was a 34.8 % reported adherence to the shoe use protocol for the flat sole shoe participants and a 52.3 % reported adherence for the rocker sole shoe group (χ^2 (1) = 2,80, p = 0.09). At twelve months, there was a 41.7 % reported adherence to the shoe use protocol for the flat sole participants and a 32.6 % reported adherence for the rocker sole group (χ^2 (1) = 0.80, (p = 0.37).

5.4.6.11 Hours of reported shoe use at each reassessment point.

The average hours that study shoes were worn per week did not differ within either group over the three reassessment points (Flat sole shoe group: $F(2,72) = 0.61$, $p = 0.54$, $\eta^2 = 0.02$; rocker sole shoe: $F(2,62) = 2.30$, $p = 0.11$, $\eta^2 = 0.07$) (Table 5.20). There was no between group difference for change in the average number of hours study shoes were worn per week over the three reassessment points ($F(2, 134) = 0.46$, $p = 0.63$, $\eta^2 < 0.01$).

Table 5.20 Reported average hours per week that study shoes were worn

Outcome measure	Assessment point	Intervention	
		Flat sole shoe	Rocker sole shoe
Average hours study shoes worn per week	6 weeks	17.0 (13.3-20.6)	18.0 (14.8-21.2)
	6 months	15.0 (10.6-19.4)	14.0 (9.9-18.0)
	12 months	14.4 (10.3-18.6)	11.9 (7.5-16.4)

Summary measures represent means (95% Confidence Intervals).

5.4.6.12 Participants' satisfaction with allocated footwear

At both six months (χ^2 (1) = 5.18, p = 0.02) and 12 months (χ^2 (1) = 6.40, p = 0.01), participants in the flat sole shoe group were more satisfied with the shoe they received than participants in the rocker sole shoe group.

The majority of participants in the flat sole shoe group were 'very' or 'extremely' satisfied with their shoe allocation at six months (26/42, 62%). At twelve months the number of participants 'very' or 'extremely' satisfied increased in the flat sole shoe group (33/45, 73%). In the rocker sole shoe group 16/43 (37%) of participants reported to be 'very' or 'extremely' satisfied with their footwear at six months (Table 5.21 and Table 5.22). At twelve months, this percentage increased to 46%, however, due to a concurrent reduction in group size, the number of participants reporting to be 'very' or 'extremely' satisfied at reassessment remained similar (16 participants at six months and 17 at twelve months).

Table 5.21 Participant's satisfaction with footwear allocation

		Satisfaction with footwear at 6 months	Satisfaction with footwear at 12 months
Flat sole shoe group	Extremely unsatisfied	0/42 (0.0%)	3/45 (6.7%)
	Very unsatisfied	1/42 (2.4%)	1/45 (2.2%)
	Somewhat unsatisfied	4/42 (9.5%)	2/45 (4.4%)
	Mixed	4/42 (9.5%)	3/45 (6.7%)
	Somewhat satisfied	7/42 (16.7%)	3/45 (6.7%)
	Very satisfied	10/42 (23.8%)	13/45 (28.9%)
	Extremely satisfied	16/42 (38.1%)	20/45 (44.4%)
Rocker sole shoe group	Extremely unsatisfied	1/43 (2.3%)	1/37 (2.7%)
	Very unsatisfied	0/42 (0.0%)	1/37 (2.7%)
	Somewhat unsatisfied	4/43 (9.3%)	6/37 (16.2%)
	Mixed	5/43 (11.6%)	6/37 (16.2%)
	Somewhat satisfied	17/43 (39.5%)	6/37 (16.2%)
	Very satisfied	8/43 (18.6%)	8/37 (21.6%)
	Extremely satisfied	8/43 (18.6%)	9/37 (24.3%)

Summary measures are numbers of participants (percentages). Denominator varies according to number of valid responses.

Table 5.22 Participants 'very satisfied' or 'extremely satisfied' with allocated footwear

	Flat sole shoe group	Rocker sole shoe group	P - value
Very/extremely satisfied at 6 months	26/42 (61.9%)	16/43 (37.2%)	0.02
Very/extremely satisfied at 12 months	33/45 (73.3%)	17/37 (45.9%)	0.01

Summary measures are numbers of participants (percentages). Denominator varies according to number of valid responses.

5.4.6.13 Consistency of exercise class at each site

Observation of the back exercise group at all sites after the last participant consenting into the study competed the group, confirmed that all groups continued to run as described in *5.3.7.2, (p75).*

5.4.6.14 Adverse events

No serious adverse events were reported. Two subjects withdrew from the rocker sole shoe group for shoe related reasons. One participant (with diabetes and poor skin condition on their feet) withdrew after wearing the shoes on one occasion, due to fear of foot blisters. The second participant who withdrew reported a blister on their heel and voiced concerns that further use of the shoes may result in further blisters. The Participant Information Sheet stated that no major adverse effects were expected, however 'as with any new footwear, participants may develop blisters as a result of wearing either shoe type.'

5.5 Discussion

This study demonstrated that in a CLBP population, people who attended a four week exercise programme and wore flat sole or rocker sole shoes reported improvements in disability (reductions in Roland Morris Disability Questionnaire score) at one year when compared to baseline. Improvement in disability was similar for both shoe groups - the flat sole shoe group reported an overall reduction in Roland Morris of 4.4 points and the rocker sole shoe group a reduction of 3.1 points. In addition, this study suggests that for people reporting pain on standing and walking, improvement in disability score, following missing data imputation, at six weeks and twelve months was significantly greater for participants in the flat sole shoe group compared to participants in the rocker sole shoe group. For people reporting pain on standing or walking, there were within-group reductions of disability in the flat sole shoe group at all reassessment points; there were no within-group changes in disability in the rocker sole shoe group. A significantly greater proportion of participants in the flat sole shoe group reported a minimal clinically important improvement in disability at six months when compared to participants wearing the rocker sole shoe. At both six months and 12 months, participants in the flat sole shoe group were more satisfied than participants in the rocker sole shoe group with the shoe they received.

5.5.1 Baseline demographic data

Participants referred for physiotherapy in this study were in their early middle age, and 66% were female - typical of a CLBP population seeking treatment within the United Kingdom (Critchley et al., 2007; Croft et al., 1998). Baseline Roland Morris Disability Questionnaire scores of 7.82 - 9.21 were similar to recent UK physiotherapy trials (Cairns et al., 2006; UK BEAM Trial Team, 2004) suggesting the sample in this study was representative of the general UK CLBP population. Although the average body mass index of participants in the current study (25.9) falls into the 'overweight' classification, this score is usual for a UK population of this age (National Audit Office, 2001). These similarities to a general low back pain population strengthen the ability to generalise findings from this study to the larger back pain population.

Participants were recruited from five sites in south west London including both inner city and suburban localities. This resulted in a diverse study population likely to be more representative of a general city population than if recruitment had occurred from one referring site.

5.5.2 Participation and attrition

Retaining 80.9% (93/115) of participants at one year compares well with other UK based physiotherapy trials in secondary care: 57% (UK BEAM Trial Team, 2004) and 73% (Critchley et al., 2007) retention have been achieved from previous studies at one year follow-up conducted in similar south London CLBP populations. The 93 participants assessed at primary follow-up point (twelve months) was one less than indicated by the sample size calculation. Although there is a small discrepancy between actual (n=93) and planned number of participants (n=94) reassessed at twelve months, with the knowledge that the results obtained between groups were similar between interventions, it seems unlikely that a type two error ('false negative' due to under powering) would have occurred in the primary clinical outcome due to this small discrepancy.

Baseline primary outcome data obtained in the study was used to recalculate the appropriate sample size based on the actual study population. For a power of 0.9 and an alpha of 0.01 based on a standard deviation of 4.86 (baseline Roland Morris Disability Questionnaire standard deviation data) and an ability to detect a four point change in the mean Roland Morris Disability Questionnaire scores between baseline and reassessment (Maughan and Lewis, 2010), the number of participants needed for each of the groups equalled 44. In this study, 49 participants in the flat sole shoe group and 44 participants in the rocker sole shoe group were assessed at the primary follow up point indicating that the study had a high probability of detecting a statistically significant result if one did occur.

Although not significant, a larger proportion of participants not completing the study had been allocated to the rocker sole shoe group. Allocation to the rocker sole group may in some way be accountable for this increased drop-out rate. Two subjects allocated to the rocker sole shoe group withdrew within the first week due to the presence of shoe related foot blisters or the fear of getting a foot blister. Other possible explanations for the slightly greater numbers lost to follow-up in the rocker sole shoe include; difficulties adapting to walking with a rocker sole; impracticalities of wearing a rocker sole style of shoe; and difficulties adjusting to the additional weight of the rocker sole shoes (which were twice the mass of the flat sole shoes). Baseline outcome measures were very similar between participants who completed and participants who did not complete the study suggesting differential attrition did not affect clinical outcomes.

5.5.3 Reasons for clinical outcomes

Regression to the mean refers to the phenomenon that a variable that is extreme on its first measurement will tend to be closer to the centre of the population distribution on a later measurement (Davis, 2007). People with conditions such as back pain generally seek medical interventions at the peak of their symptoms (Dunn et al., 2006), and that natural improvement is likely to follow. In this study the greatest change in reduction in disability occurred at the six week assessment. During this time participants started wearing the allocated shoes, and completed the low back exercise programme. Both groups also showed improvement in reported disability at twelve months when compared to baseline. Due to the lack of a non-treatment group it is not possible to determine how much of the changes reported at six weeks and twelve months were predominantly attributable to regression to the mean, the immediate or long term effects of attending the exercise class, or the immediate or long term influence of the footwear received.

A randomised controlled trial (Costa et al., 2009) endeavoured to clarify whether positive intervention results, such as the within group reductions in disability demonstrated in the current study, may in fact be due to participants' regression to the mean. Costa et al. (2009) conducted a research trial (n=154) with an exercise intervention arm and a placebo-controlled arm. There was no difference between groups in reduction of Roland Morris Disability Questionnaire score at the twelve month assessment. These findings support the suggestion that the within group reduction in disability in the current study may have resulted from regression to the mean, and not from the effect of the interventions.

A 'placebo effect' has been defined as "a genuine psychological or physiological effect, in a human or another animal, which is attributable to receiving a substance or undergoing a procedure, but is not due to the inherent powers of that substance or procedure" (Stewart-Williams and Podd, 2004). In this study, a pragmatic control group, allocated flat sole shoes, was used as a comparison to the rocker sole shoe group. The allocation of a shoe to the 'control' group aimed to reduce the possibility that study findings, if demonstrating significance in the rocker sole shoe, were related to a placebo effect of receiving 'a' pair of shoes as opposed to potential benefits resulting from the structure of the shoe.

Although both groups received footwear, hence introducing the potential for a placebo effect in both groups, due to media and marketing surrounding the rocker sole shoe during the trial it is likely that any placebo effect would have favoured people in the rocker sole shoe group (Shiv et al., 2005). However, due to the lack of difference observed in this study between the two groups, if a positive placebo effect did occur in the rocker sole shoe group it may have been too small to result in differences between the groups or may have been negated by an effect associated with the footwear, such as a biomechanical effect disadvantageous to those with CLBP.

Timing of follow-up assessments may have been a contributing factor to the results obtained. The initial follow-up assessment occurred at six weeks. During this time participants also attended up to four low back exercise groups. It is well documented that improvement in disability is likely to occur following such a six week exercise intervention period (Cairns et al., 2006; Critchley et al., 2007; Lewis et al., 2005; UK BEAM Trial Team, 2004). Improvement in disability associated with attendance to the exercise group may have overshadowed any change in disability directly associated with footwear use. However, a general exercise approach is a current best practice intervention for those with CLBP hence it may be deemed unethical to remove this input from a patients care.

It is possible that clinical differences did occur between groups, but were not detected by the outcome measures assessed. Although the primary outcome assessed disability, a range of measures, sensitive to clinical change and in accordance with the recommendations of Deyo et al (1998) and Bombardier (2000) were additionally completed. These aimed to detect change in pain, functional activity (specific to each participant), anxiety and depression, fear of movement, general health status, time off work, and lumbar impairment measures. There were no between group differences for any of the measures assessed over the four time points. This adds strong support to the study conclusions that clinical difference between the groups did not occur.

A further explanation for similar clinical outcomes between groups is that treatment effects resulted from changes in psychological and social factors. The low back exercise group educated both groups on pain, managing a flare-up, and the benefits of exercise and relaxation. In addition, both groups were encouraged to walk for two hours a day, possibly increasing their daily activity level when compared to pre-study activity levels. Furthermore, participants in the study had regular reassessment over the duration of the study with the C.I., who offered encouragement to maintain their exercise programme. Increasing activity level (NICE, 2009), improving coping strategies (Linton, 2000), and higher levels of therapist supervision (Hayden et al., 2005c) have all been demonstrated to improve clinical outcome in those with CLBP.

A pre-planned sub-group analysis demonstrated that in participants reporting baseline low back pain on standing or walking, disability improved less for those allocated to the rocker sole shoe group than for those allocated to the flat sole shoe group. Although this sub-group analysis did not undergo an *a-priori* power calculation to determine appropriate sample size, standard deviation data of the primary outcome measure from the sub-group sample was used to determine the sample size that would be needed in order to ensure conclusions were statistically viable: for a power of 0.8 and an alpha of 0.05 based on a standard deviation of 5.26 (standard deviation data collected from the sub-group of participants reporting baseline low back pain on standing or walking) and an ability to detect a 4 point change in the mean Roland Morris Disability Questionnaire scores between baseline and reassessment, the number of participants needed for each of the groups equalled 28. The flat sole shoe sub-group for those reporting pain on standing and walking totalled 30 participants and the rocker sole shoe sub-group totalled 29 participants. Therefore, this sub-group analysis had appropriate power.

If enough hypotheses are tested, on different sub-sets of the data, the likelihood that some will appear to be 'falsely' statistically significant may increase (Lord et al., 2004). This may account for the significant finding in the sub-group reporting pain on standing or walking. However, in this study, the knowledge that only one sub-group analysis was conducted, that it was pre-planned (i.e. the findings did not arise from exploratory data analysis) and that the sample size of the subgroup had appropriate power, improve confidence that the findings are true.

5.5.4 Comparison of findings with other studies investigating the effect of rocker sole shoes in people with chronic low back pain

The only identified randomised controlled trial investigating rocker sole footwear in LBP (Nigg et al., 2009) reported a non-clinically important reduction in pain in male golfers at six weeks compared to normal footwear. This finding concurs with the absence of clinical improvement in pain in the current study in either footwear group at six weeks. Disability scores were not assessed by Nigg et al. (2009), nor were other relevant outcome measures, recommended when assessing those with CLBP (Bombardier, 2000; Deyo et al., 1998), such as health status, satisfaction and time off work, hence further between study comparison cannot be made.

5.5.5 Can certain footwear be detrimental to chronic low back pain?

Researchers have observed an increase in centre of pressure sway in people with CLBP compared to asymptomatic individuals in numerous studies (Brumagne et al., 2008; Della Volpe et al., 2006; Mok et al., 2004) and have hypothesised that proprioceptive rehabilitation may be beneficial as a treatment option to reduce this dysfunction with the view to reducing symptoms of LBP. The current study suggests that for people with CLBP the use of a rocker sole shoe, adding instability to the lower limb whilst standing and walking offers no greater improvement in their symptoms than if a flat sole shoe is worn. Furthermore, for those reporting difficulties with standing or walking due to their low back pain, wearing a rocker sole shoe may be detrimental to the level of improvement reported.

The concurrent biomechanical study conducted in this thesis investigates the effect of shoe type on centre of pressure displacement over time *(Chapter 7, p148).*

It may be that although proprioceptive rehabilitation is recommended for people with CLBP, the use of a rocker shoe (which in asymptomatic individuals may increase medio-lateral centre of pressure displacement by approximately 100% and antero-posterior displacement by approximately 50% (Nigg et al., 2006b)) may present too great a challenge for those individuals reporting pain on standing or walking. It has been suggested that due to the presence of pain, those with low back pain may co-contract muscles around the lumbo-pelvic region (Radebold et al., 2000). Furthermore, the presence of pain has been associated with inhibition and delayed contraction (Hodges and Richardson, 1998; Hodges and Richardson, 1999) of spinal postural stabilising muscles. These observations have been proposed to detrimentally affect the initiation of appropriate balance strategies (Mok et al., 2004). For the sub-group of participants reporting pain on standing or walking, and hence, the sub-group more likely to be in pain whilst wearing their footwear, the added instability offered by the shoes, accompanied by potential pain induced spinal muscle inhibition and co-contraction, may have contributed to the reduced improvement in disability when compared to improvement in those not reporting pain on standing or walking.

High levels of anxiety have been suggested as dominant psychological risk factors contributing to the presence of CLBP (Linton, 2000). Further exploration of data demonstrated that the rocker sole shoe sub-group, reporting pain on standing or walking, had an above average mean (standard deviation) anxiety score at baseline when compared to the study population (8.97 (3.89) compared to 7.63 (3.89) respectively), whereas the flat sole shoe sub-group reported lower anxiety (6.97 (3.70)). Although the role of anxiety as a predictor for outcome in low back pain remains unclear (Frymoyer and Cat-Baril (1987) reported that baseline psychological variables did not predict long term disability outcome, whereas opposing findings were reported by van Doorn (1995)), it may be that baseline anxiety levels contributed to the reduced improvement in disability in the rocker sole shoe sub-group.

5.5.6 Implications for clinicians

This is a novel study investigating effects of rocker sole shoes on a CLBP population and provides clinicians with evidence from a relatively large clinical trial. Based on the findings of this study, clinicians should feel confident to advise patients with CLBP that if the patient does not report pain when standing or walking a rocker sole shoe may offer a similar outcome when compared to a flat sole shoe. If a patient reports pain with standing or walking it may be more beneficial to wear a flat sole shoe than a rocker sole shoe. The findings in this study do not warrant a change in practice in the management of CLBP from current best-practice proposed in the NICE guidelines (2009).

5.5.7 Strengths and limitations

5.5.7.1 Unmasking of group allocation

Face-to-face assessment by the C.I. may have inadvertently resulted in unmasking of group allocation due to comments made by the participants regarding their footwear. For example, inadvertently describing the colour of the shoe (different between the two shoe groups) or using descriptors such as feeling ‘wobbly’ whilst in the shoes. The failure of the process to blind the assessor to the patient group on some occasions may have introduced a degree of bias to the results; however, no results were analysed until data from all participants had been collected in an attempt to minimise bias.

5.5.7.2 Hours of shoe wear

Results obtained from completion of the study diary sheets relied on accurate self-reporting of shoe use from participants. It is acknowledged that this method of reporting may not be accurate (Moseley, 2006) with a tendency to overestimate adherence by approximately 10 % (Moseley, 2006). However, there does not appear to be a reason why those in the rocker sole shoe group would be more prone to inaccurate recall of such data than those in the flat sole shoe group, hence any inaccurate reporting is unlikely to bias the results.

Although participants were asked to report 'hours of shoe wear per day' whilst standing and walking, not sitting, it was not deemed feasible to expect participants to report with this degree of precision. However, it is unlikely that the ratio of time spent standing and walking, to sitting would vary between groups, hence unlikely to bias the results.

5.5.8 Further research

It is not possible to determine whether the use of either footwear type resulted in an increased improvement in disability, a reduced improvement in disability or offered similar outcomes in disability to patients not in the research study but who also attended the exercise class. Conducting a similar trial comparing a flat or rocker sole shoe group with a patient's normal footwear would answer this query. However, as flat sole sports shoes are likely to be a very common 'normal' shoe choice, findings from such a study are unlikely to differ from those in the current study.

Many studies investigating the effects of exercise interventions on LBP have reached similar conclusions - the greatest improvement in pain or disability or both tends to occur at the first reassessment point following the study intervention, followed by a general but more gradual reduction in the primary outcome measure over time (Cairns et al., 2006; Critchley et al., 2007; Lewis et al., 2005; UK BEAM Trial Team, 2004; van Tulder et al., 2006). It is not clear how much of this improvement may be due to the intervention and how much may be due to regression to the mean, or the natural history of the condition. Although exercise, as proposed in national (NICE, 2009) and international guidelines (Airaksinen et al., 2006; Koes et al., 2001), is deemed a current best practice for CLBP and appears to offer improvement in most randomised controlled trials (Cairns et al., 2006; Critchley et al., 2007; Lewis et al., 2005; UK BEAM Trial Team, 2004) it may be that mechanistic pathways that are uninfluenced or less influenced by exercise are also contributing to the presence of such a long standing recurrent condition. More recently, it has been suggested that central brain changes (reductions in volume in the dorso-lateral pre-frontal cortex and changes in biochemical composition (Grachev et al., 2000; May, 2008; Rodriguez-Raecke et al., 2009)) in regions thought to be associated with the transmission of pain, and sensory-motor feedback may be contributing to some of the symptoms of LBP. This will be discussed further in *Chapter 10 (p210)*. Further research into such potential underpinning mechanisms of CLBP is needed. Results from such research may direct novel management approaches which in addition to exercise may result in greater improvement for people with CLBP than exercise alone.

5.6 Conclusions

This study is the first randomised, controlled trial with long term follow-up to assess the effects of rocker sole shoes in chronic low back pain. Results of this study can offer clinicians robust evidence to guide patients towards the appropriate choice of footwear for those with chronic low back pain.

- Change in self-reported pain and disability scores were similar between groups over all follow-up points.
- A greater proportion of participants who wore the flat soles shoes reported a clinically important change in self-reported disability at six months.
- For those reporting pain on standing or walking, a greater reduction in disability was observed in those wearing flat sole shoes than those wearing rocker sole shoes at six weeks and twelve months.
- At both six months and twelve months, participants in the flat sole shoe group were more satisfied than the participants in the rocker sole shoe group with the shoe they received.
- It is not clear from this study if either shoe offers additional benefits to the reduction of disability obtained from attendance to an exercise class alone (a current best practice).
- Based on the findings of this study those with chronic low back pain can be informed that use of either shoe type is likely to result in a similar clinical outcome at one year. However, if a person's chronic low back pain is predominately aggravated by standing or walking it may be more beneficial to wear a flat sole sports shoe than a rocker sole sports shoe.

6 Methods used in the biomechanical studies

6.1 Chapter summary

This chapter presents the development of methodologies common to the three biomechanical studies in *Chapter 7 (p148), Chapter 8 (p170) and Chapter 9 (p189).*

6.2 Introduction

The biomechanical section of this thesis includes three studies: 1) the short and long term influence of rocker sole and flat sole shoes on postural control whilst standing in people with CLBP *(Chapter 7, p148)*; 2) the short and long term influence of rocker sole and flat sole shoes on gait in people with CLBP *(Chapter 8, p170);* and 3) a cross sectional study to compare gait and postural control in standing in people with CLBP to age- and gender-matched asymptomatic individuals *(Chapter 9, p189).* This chapter outlines the development of methods common to all three biomechanical studies namely, the recruitment of participants with CLBP, choice of outcome measures, protocol for motion analysis marker placement, protocol for obtaining anthropometric measurements, protocol for assessment of standing and walking trials, and the extraction of clinically relevant parameters from gait laboratory data.

6.3 Choice of motion analysis system

Several systems are available for the measurement of human kinematics (the study of movement of body segments). The electro-goniometer, an electronic version of the goniometer, is a basic system, commonly used in clinical practice to assess joint angles. Two brackets are attached to the segments either side of the joint under assessment. Although an easily accessible assessment tool, providing immediate results, the accuracy of the data obtained depends on the correct placement of the brackets to correctly assess the axis of rotation at the joint of interest (Kirtley, 2006). In addition, the straps attaching the brackets to the body segments may move during gait, reducing measurement accuracy (Chao, 1980). Furthermore, these devise are mainly used to obtain two not three dimensional data. Flexible goniometers reduce the errors associated with joint centre alignment, however, can be restrictive to a participants gait due to associated cabling. Furthermore, although able to measure motion between two adjacent segments, they do not have the ability to inform on absolute motion of body segments in space (Kirtley, 2006).

To assess such absolute motion, measurements must be taken with respect to a fixed global reference system. This can be done through: optical tracking, whereby skin marker locations are digitized from images recorded by a video camera; electromagnetic motion analysis systems; ultrasonic motion analysis systems, which utilise the delay in sound transmission through air to triangulate the position of ultrasound emitting markers; or inertial systems, which utilise a combination of miniature micro-electro-mechanical system sensors (Kirtley, 2006). Three dimensional optical methods are currently the favoured approach for clinical gait analysis (Kirtley, 2006), hence, the method of choice to assess postural control and gait in the current studies.

Although a favoured approach, limitations and measurement errors are reported with this assessment technique. Firstly, some error will occur in the accuracy of body marker placement. Secondly, further error may occur when digitising the position of the body markers. Such inaccuracies in the coordinates recorded result in what is known as digitization noise. Much of this noise can however be filtered by an appropriately chosen cut-of frequency to separate the wanted signal from the unwanted noise, improving accuracy of the data obtained. Digitisation errors for marker location are dependent on specific systems, however, for modern hi-resolution systems such as the system used in this study, these are very small (less than one millimetre) (Chester et al., 2005). Errors are more likely to arise from the anthropometric model used to calculate joint centres and axes of rotation of the major joints, such as the hip, knee and ankle (Della Croce, 2005; Leardini, 2005) though in near normal walking in adults these are quite small (Stagni et al, 2004). Greater errors occur when investigating spinal motion or motion in the foot for three main reasons: i) the segments are small; ii) joint motions may not conform to a simplistic model, such as a hinge of ball and socket joint); c) relative skin to segment motion may be larger (Bruening et al. 2012; Ranavolo, et al. 2013).

6.4 Choice of marker set

The Modified Helen Hayes marker set, the conventional biomechanical model for calculation of joint centres and subsequently of joint kinematics during movement, was implemented in the current study (Davis et al., 1991). The model is based on the placement of 13 retro-reflective markers on the following anatomical locations: left and right ASIS, spinous process of the second sacral vertebra, left and right lateral thigh, left and right lateral femoral condyle, left and right lateral shank, left and right lateral malleoli, and the left and right second metatarsal head. In the current study, additional markers were placed on the spinous process of the cervico-thoracic junction, left and right acromion, left and right Iliac crests, and left and right posterior calcanei.

6.5 Choice of software to derive kinematics and kinetics

In clinical gait laboratories, the Vicon system accompanied by the Modified Helen Hayes model as implemented in the Vicon Clinical Manager software is commonly used. Vicon Nexus and Polygon (Vicon Motion Systems, Oxford, UK) were utilized in the biomechanical studies to derive the biomechanical parameters of interest. This system has shown good within and between session repeatability in the assessment of lower limb biomechanics (Yavuzer et al, 2008; Wilkin et al., 2012). The Plug-in-Gait model for deriving joint kinematics is based on the Davis model (Davis, 1991) and is often used in clinical research and applications. Although the model tends to produce systemic errors in the location of the hip joint centre, these result in only small errors in computed kinematics (Stagni et al., 2004).

6.6 Choice of biomechanical outcome measures

The biomechanical studies did not aim to investigate the full biomechanics of standing and gait, but instead aimed to investigate specific measures that:

> i)may be influenced from wearing rocker sole shoes compared to flat sole shoes – such measures were selected from the analysis of results of previous studies that had investigated difference in lower limb biomechanics when standing and walking in rocker sole shoes compared to flat sole shoes, and:
>
> ii) have been demonstrated by research to differ significantly between people with and without CLBP hence proposed as causative factors in the presence of CLBP.

For example, antero-posterior displacement of the centre of pressure (*6.11, p142*) was analysed, but medio-lateral displacement was not - when standing in rocker sole shoes the greatest displacement of the centre of pressure (CoP) occurs in the antero-posterior direction (Nigg et al., 2006b), hence, it was anticipated that movement in this direction would demonstrate the greatest changes between the rocker sole shoe and barefoot or flat sole shoe comparisons. Furthermore, the hip and ankle strategy predominantly displace the CoP in the antero-posterior direction, hence this outcome parameter was deemed of greatest relevance to assess. Similarly, due to the expected greater displacement of the CoP in the antero-posterior direction, due to the convex nature of the sole in the antero-posterior direction, sagittal plane kinetics and kinematic parameters were analysed, whereas frontal and transverse plane parameters were not. The biomechanical parameters of interest are presented in *6.11 (p142)*.

6.7 Recruitment of participants with chronic low back pain

Commencing with the 60th participant in the main clinical investigation (REC 09/H0706/4) participants were requested to consider participating in the biomechanical studies. At this stage they were unaware of their shoe allocation *(5.3.2, p63).* Potential participants were provided with the Patient Information Sheet by a physiotherapist at one of the five referring research sites for the main clinical study (09/H0706/4). They were also provided with a Patient Information Sheet for the biomechanical studies *(11.26, p297)*. A total of twenty participants who had consented into the main clinical study also expressed an interest to additionally participate in the biomechanical study. These twenty participants were recruited from the following four sites:

- Balance Performance Physiotherapy, Clapham, London SW4
- Chelsea and Westminster Hospital, Chelsea, London SW10
- Kingston Hospital, Kingston, Surrey, KT2
- St. George's Hospital, Tooting, London SW18

On entering the biomechanical studies participants were already randomised into either the rocker sole or the flat sole group, in accordance with the randomisation for the main clinical study. Inclusion and exclusion criteria (Table 6.1) were similar to those in the main clinical study *(Table 5.1, p64),* with the addition of the following inclusion criteria:

- Participants consented to participant in the main clinical study (09/H0706/4)
- Participants must be able to travel to Guy's Hospital, London

Table 6.1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Aged 18 to 65 years • More than 3 months of continual or recurrent episodes of LBP • Lumbosacral pain with or without referral (of a non-radicular nature) • Pain of a mechanical nature (pain aggravated by activity) • Willing to comply with the randomisation process • Able to fully communicate in English • Able to participate in an exercise group and perform exercises at home • Participants must have consented into study REC: 09/H0706/4 • Participants must be able to travel to Guy's Hospital, London, SE1	• Constant pain • Non mechanical pain (pain that is not aggravated or eased by activity or posture) • Nerve root entrapment accompanied by neurological deficit • Neoplasms • Severe structural deformity or osteoporosis • Known spondylolysthesis or spinal stenosis • Fracture of the spine within the past year • Inflammatory disease of the spine • Spinal infection • Severe cardiovascular/ metabolic disease • Pregnancy • Previous spinal surgery • Known Morton's Neuroma • Skin ulceration over the foot • Peripheral neuropathy with loss of sensation • History of falls • Surgery to the lower limb in the past 8 weeks • Participants with history of deep vein thrombosis (DVT) yet to be stabilised /yet to be advised to return to exercise by their medical practitioner. • Participants undergoing prolonged unresolved legal issues regarding their back pain • Participants who have previously used rocker sole shoes

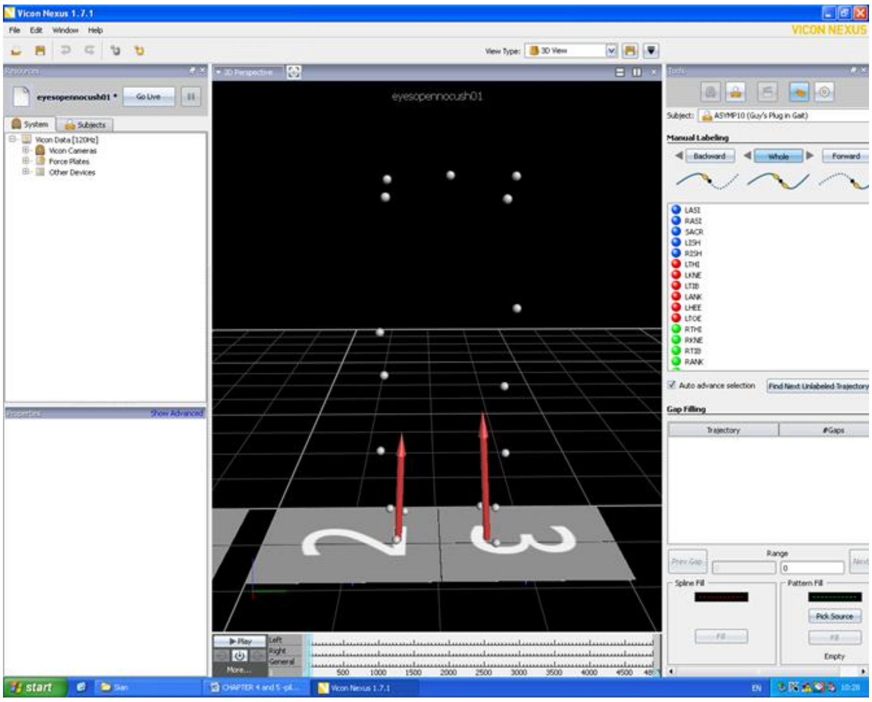
6.8 Gait laboratory equipment

6.8.1 Motion analysis system

The motion analysis system consisted of seven T10 cameras (Vicon Motion Systems, Oxford, UK). The system depends on the accurate attachment of retro-reflective markers (Vicon Motion Systems, Oxford) (Figure 6.1) to specific bony landmarks. These were captured in three-dimensional space at a rate of 120 Hertz (Hz). The three-dimensional position of the marker can be calculated once it is visible to two cameras at the same time point (Figure 6.2).

Figure 6.1 Retro-reflective marker

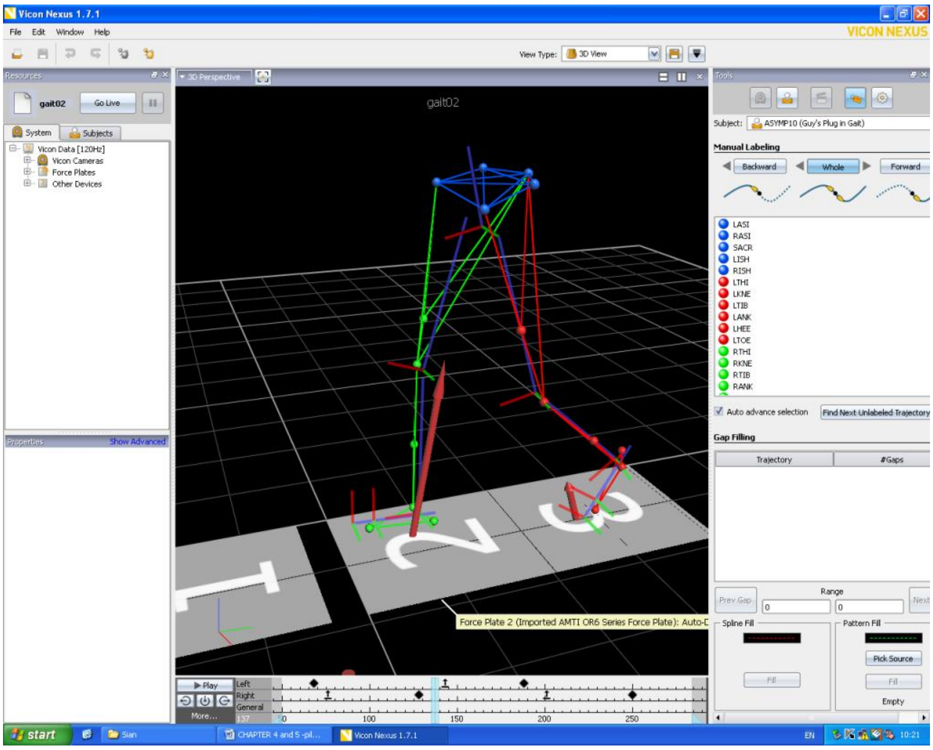
Figure 6.2 Visualisation of retro-reflective markers (white dots) by the motion analysis camera system



6.8.2 Force plates

Ground reaction forces (GRFs) across three planes were captured using three ground mounted force plates (FP5000, AMTI Inc., Massachusetts, USA), placed in line. The force data were integrated with the Vicon software, allowing for the calculation of joint moments (rotation joint forces) from the kinematic and GRF data by inverse dynamics (Kirtley, 2006). Force plate data were captured at a rate of 1080Hz, synchronised to the camera frequencies (precisely nine force plate samples per camera frame). Figure 6.3 shows a participant striking the second and third force plate during a gait trial, with real time capture of a ground reaction force (vertical red arrow), used to calculate joint moments, by the Vicon system.

Figure 6.3 Participant striking the force plate during a gait trial (ground reaction force shown by the vertical red arrow)



Two force plates were used to calculate joint moments within each limb, whilst standing, using an inverse dynamics approach (Kirtley, 2006). Inverse dynamics involves the modelling of the human body as a series of linked segments each with certain inertial properties (for example, mass and radius of gyration) (Kirtley, 2006). The forces acting on the body are both inertial (acceleration of the body segments) and external forces (for example, the ground reaction force) (Winter, 2009). The method of calculation proceeds by resolving distal forces and moments using the ground reaction force, then uses the resolved values, to resolve moments and forces at more proximal joints (Kirtley, 2006). A free body diagram is drawn for each segment (for example, the foot, the shank, and the thigh), with calculations starting from the foot and working up.

6.9 Methodological considerations in three-dimensional motion analysis

6.9.1 Calibration of the gait laboratory

Prior to each participant's assessment the force plates and motion analysis cameras were calibrated as described in the One Small Step gait laboratory calibration protocol *(11.27, p302).* This aimed to improve accuracy of the gait laboratory equipment in the data collection process.

6.9.2 Anthropometric measurements

Anthropometric data informs the mechanical model formulated for each participant in Nexus (Vicon's capture software [Vicon Motions systems, Oxford, UK]) *(6.10.3, p134)*. The anthropometric measurements assessed are presented in Table 6.2 and in Figures 6.4 to 6.7. The calibration of anthropometric measuring equipment is presented in *11.28 (p305).* The seated weighing scales (Weightcare chair scale, Marsden Weighing Machine Group, Henley-on-Thames, UK) were calibrated every six months to ensure accuracy of measurements *(11.28, p305).*

Table 6.2 Anthropometric measurements

Anthropometric measure	Description	Measuring device [units]
Pelvic width	Distance between the inferior aspect of the left and right anterior superior iliac spine	Large calliper [mm]
Leg length	In supine, distance from the inferior aspect of the anterior superior iliac spine to the inferior aspect of medial malleolus (left and right)	Tape measure [mm]
Knee width	In supine, knees in extension, distance between the lateral femoral epicondyle at the lateral aspect of the knee joint line and the midpoint of the medial collateral ligament at its intersection with the knee joint line (left and right)	Small calliper [mm]
Ankle width	In supine, knees in extension, distance between the most medial point of the medial malleolus and the most lateral point on the lateral malleolus (left and right)	Small calliper [mm]
Height	The head was measured in the Frankfurt plane, a standard plane established by an imaginary line passing through the right tragion and the lowest point of the right eye. The vertical distance from the floor to the vertex of the head, its highest point in the mid-sagittal plane, was measured with the participant standing barefoot	Stadiometer [mm]
Weight	Seated in weighing scales wearing shorts and short sleeved shirt.	Seated scales [kg]

Legend: mm: millimetres; kg: kilogramme

Figure 6.4 Measurement of pelvic width

Figure 6.5 Measurement of leg length

Figure 6.6 Measurement of knee joint width

Figure 6.7 Measurement of ankle joint width

6.9.3 Marker placement

Twenty infra-red reflective markers (14mm diameter) were positioned on each participant by the same researcher (Dr Adam Shortland [AS]) at each testing session. This researcher was highly experienced in the use of the motion analysis system and positioning of the motion markers (Gough et al., 2004; Gough and Shortland, 2008; McNee et al., 2009). Identification of joint centres depends heavily on accurate marker placement (Kratzenstein et al., Epub ahead of print). Particular attention must therefore be given to minimising errors associated with marker placement. A standard protocol for marker placement was used to maximize consistency and repeatability of the data collection process *(11.29, p307, Table 6.3)*. Table 6.3 describes the location and anatomical landmarks used in the placement of markers. Figure 6.8 demonstrates the body marker placements for the barefoot trials.

Table 6.3 Description of marker placement

Marker label	Description
Sacrum	A marker was placed over the sacrum between the posterior superior iliac spines as palpated by the examiner.
Anterior superior iliac spine (ASIS)	A marker was placed over the left and right ASIS
Posterior pelvic markers	A marker was placed at the midpoint of an imaginary line between the sacrum marker and the left ASIS marker and the sacrum marker and the right ASIS marker
Knee	A marker was attached over the lateral aspect of the left and right knee joint line
Thigh	A marker was placed over the lateral aspect of the left and right thigh in the plane defined from an estimate of the hip joint centre and knee flexion axis.
Ankle	Ankle markers were placed over the most lateral aspect of left and right lateral malleoli.
Shank	A marker was placed in the plane defined by the knee joint centre and the ankle flexion axis.
Forefoot	A marker was placed between the second and third rays proximal to the equinus break.
Heel	A marker was placed on the posterior aspect of the left and right calcanei, at the same height as the forefoot marker
Shoulder	A marker was placed over the most lateral aspect of the left and right acromion
Cervico-thoracic junction	A marker was placed over the spinous process of the 7th cervical vertebra

Figure 6.8 Body marker placements

6.9.3.1 Placement of retro-reflective markers on study footwear

Assessment of participants in their study shoes required foot markers to be removed and replaced onto the footwear. The co-researcher (AS) removed the 2^{nd} metatarsal head marker, and the calcaneum marker from each foot in order for participants to put on their study shoes. The outer material design of both shoes consisted of retro-reflective strips. Due to the motion analysis system perceiving these reflective strips as markers, the co-researcher covered all reflective strips with non-transparent sticky tape (Figure 6.9 and Figure 6.10). Study shoes were then put on, and the removed markers were replaced onto the shoe overlying the relevant anatomical sites of the head of the 2^{nd} metatarsal and the posterior calcaneum (Figure 6.9 and Figure 6.10). The toe marker was placed on the shoe proximal to the equinus break. Toe and heel markers were placed on the shoes at an equal height from the ground.

Figure 6.9 Flat sole shoe with retro-reflective regions covered, and footwear marker placement

Figure 6.10 Rocker sole shoe with retro-reflective regions covered, and footwear marker placement

6.10 Gait laboratory assessment

Participants in the biomechanical investigation attended for assessment at the Guy's Hospital gait laboratory on three occasions at:

- baseline
- six weeks
- six months

In comparison to individuals participating in the main clinical study, participants in the biomechanical study attended three additional assessments when compared to those participating only in the main clinical study. Participants in the biomechanical study did not receive additional treatment to those participating only in the main clinical study (09/H0706/4). Following initial assessment at their referring site for consent into the main study, participants were instructed not to wear their allocated study shoes until the assessment in the 'One Small Step' Gait laboratory, Guy's Hospital. They were asked to bring their study shoes with them to each gait laboratory assessment, and to keep them hidden in a bag to ensure that the chief investigator (C.I.), blinded to group allocation, did not see the shoes. The initial gait laboratory assessment took place within a week of a participant's baseline assessment for the main clinical study.

6.10.1 Development of standing trial assessments

6.10.1.1Trial conditions

During more challenging standing conditions, people with LBP have been shown to present with differing postural control to people without (Byl and Sinnott, 1991; Della Volpe et al., 2006; Luoto et al., 1996; Mientjes and Frank, 1999; Mok et al., 2004; Moseley and Hodges, 2005; Takala et al., 1997b). Therefore, in the current study, and in concurrence with other research studies investigating the effect of CLBP on postural control during standing (Brumagne et al., 2008; Della Volpe et al., 2006; Mientjes and Frank, 1999; Mok et al., 2004; Salavati et al., 2009b), participants were assessed during four different standing conditions. These involved the manipulation of visual input (eyes open or eyes closed) and support surface (firm or compliant). The following standing conditions were assessed:

(1) firm ground with eyes open
(2) firm ground with eyes closed
(3) compliant ground with eyes open
(4) compliant ground with eyes closed

Compliant surfaces represent a more challenging standing surface. This was achieved by placing an Airex™ cushion (48.5 x 40.0 x 6.4 cm, 0.7kg), made of high density (50kg/m^3), closed-cell foam, (l-group, St. Louis, MO) over each force plate (Figure 6.11).

The removal of visual input was used to provide an additional challenge to the postural control system (Mann et al., 2010) and aid in the detection of potential postural control differences between groups. Furthermore, data obtained with visual occlusion has been shown to have higher reliability than data obtained with eyes open, although both conditions have demonstrated acceptable reliability (Ruhe et al., 2010).

6.10.1.2 Number of trial repetitions

Although it has been suggested that three to five trials is most appropriate for obtaining reliable centre of pressure (CoP) parameters (Ruhe et al., 2010), due to the presence of CLBP in study participants and the number of trial conditions also under investigation it was decided to conducted three trial repetitions for each standing condition. The averaging of three trials has been shown to produce acceptable reliability for the majority of CoP parameters when assessing musculoskeletal disorders (Salavati et al., 2009a).

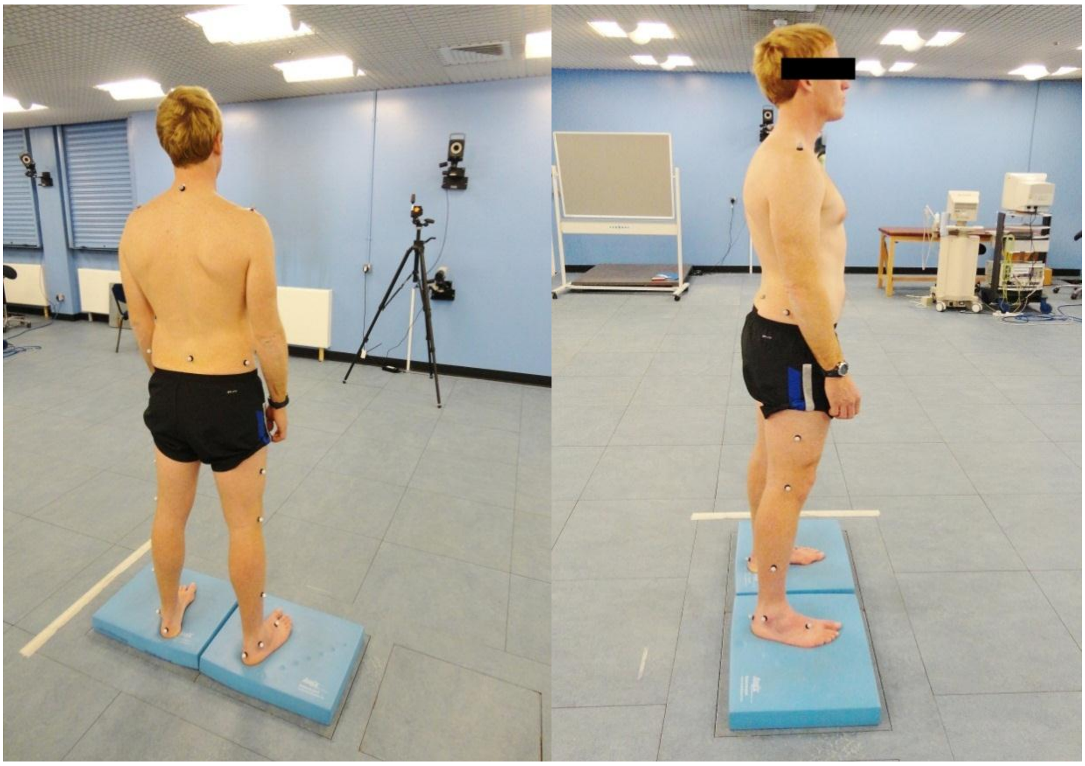
6.10.1.3 Trial duration

Reliable CoP measurements have been reported from trials of 30 second durations (Pinsault and Vuillerme, 2009; Salavati et al., 2009a). In the current study, 40 seconds of trial data were recorded with data from only the middle 30 seconds of each trial analysed. This aimed at avoiding any initial sway errors occurring whilst attaining the standing starting position, and removing the possible effects of either fatigue at the end of each test, or participant's anticipation of a trial reaching its end. A systematic review investigating acceptable reliability for CoP parameters in asymptomatic individuals, published subsequently to the start of the current study, recommended a minimum trial duration of 90 seconds (Ruhe et al., 2010). However, in the current study sample, prolonged standing may have aggravated symptoms, and negatively influenced attrition rates.

6.10.1.4 Standardised visual focus point

During trials with eyes open participants were requested to keep their eyes focused on a red sticker placed on a tripod three metres in front of them at eye height (Figure 6.11). Deviations in eye focus have been shown to influence postural control (Ivanenko et al., 1999), hence, standardisation of gaze orientation aimed to increase data reliability.

<u>Figure 6.11 Standing under more challenging conditions on foam cushions</u>

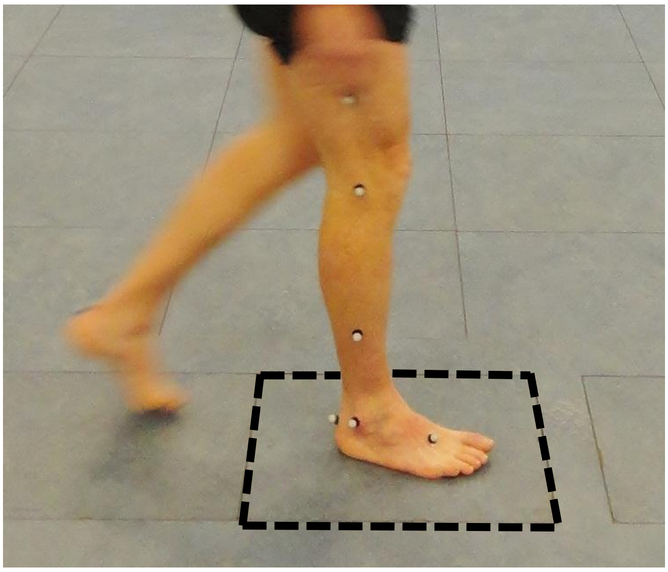


6.10.2 Development of gait trial assessments

6.10.2.1Clear force plate strikes

The assessment of gait required each participant to attain three clear force plate strikes for both the left and the right foot. A clear force plate strike required a heel strike and toe off to occur with the foot making contact with one plate only, and without contacting the force plate with the contralateral foot (Figure 6.12). If, after several attempts, the required clear force plate heel strikes were not obtained, participants were asked to alter their starting position by taking half a step backwards, and the collection of further trials continued.

Figure 6.12 Clear force plate strike with right leg



Borders of the force plate outlined by the dashed line added to figure for clarification

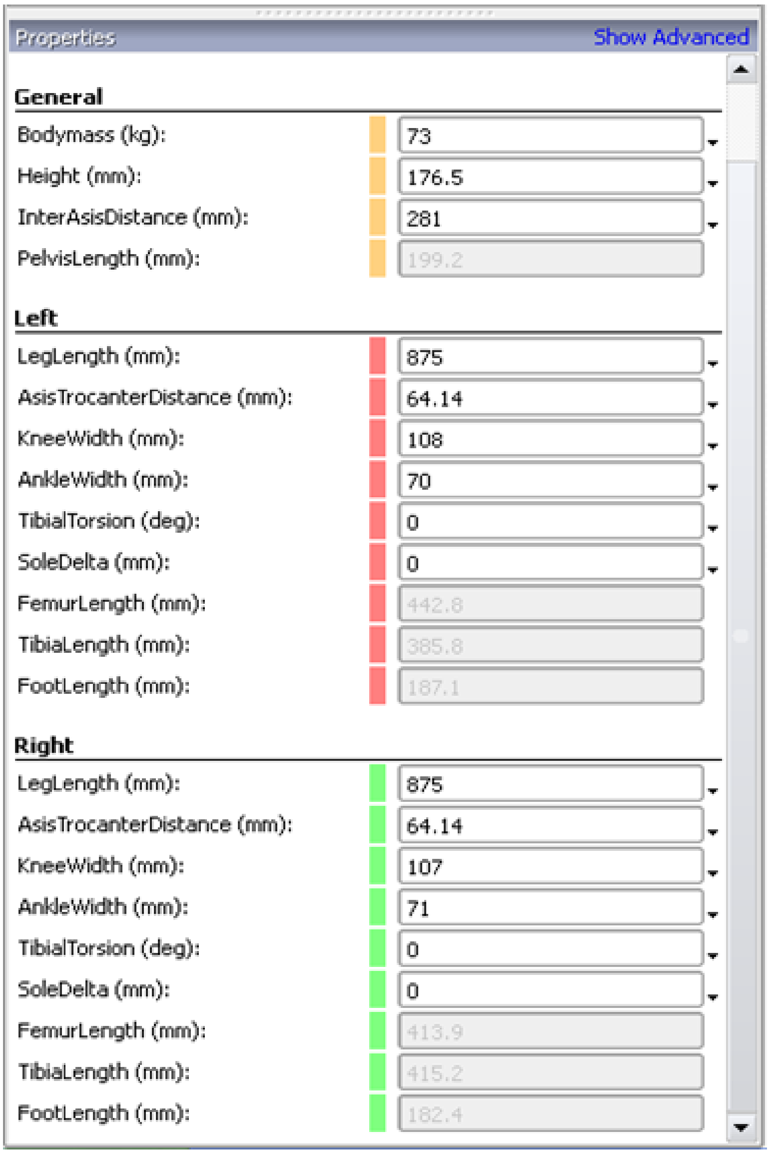
6.10.3 Data collection and processing of standing and gait trials

Video and analogue data captured by the motion capture system were processed using proprietary software in Nexus v1.7, (Vicon Motion Systems, Oxford,UK) using the Plug-in-Gait (PiG) model to generate the spatio-temporal, kinematic and kinetic data of interest. Collecting and processing trial data occurred in several stages, each of which will be described below.

6.10.3.1 Association of instrumented data with the anthropometric data collected from the participant.

Participants' anthropometric data (*6.9.2, p123*) were inputted into Nexus (Figure 6.13) by the C.I. in order to determine lower limb joint centres *(6.10.3.2, p136).*

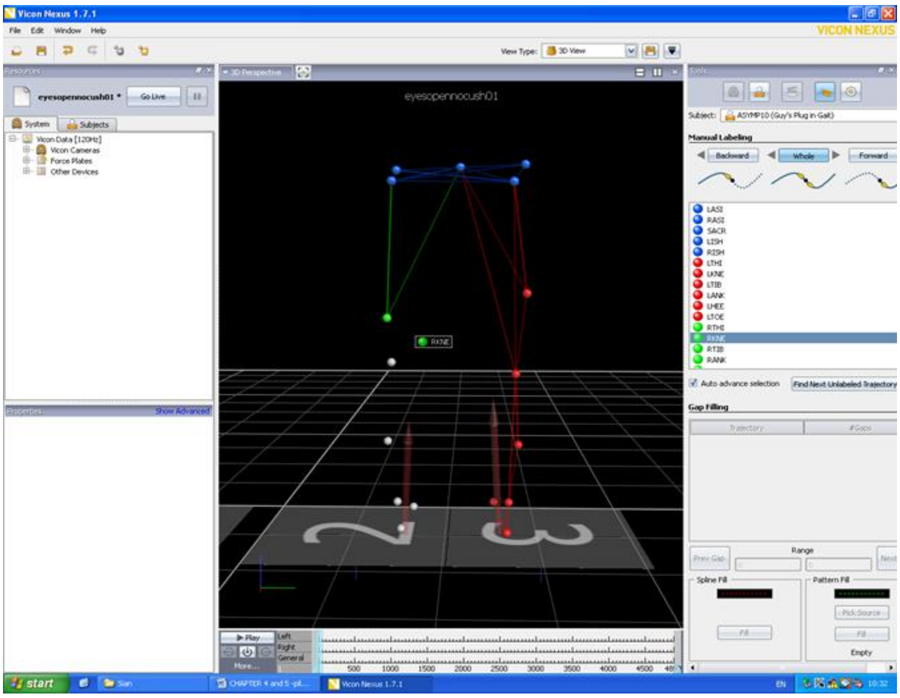
<u>Figure 6.13 Inputting of anthropometric data into Nexus</u>



6.10.3.2 Static calibration trial

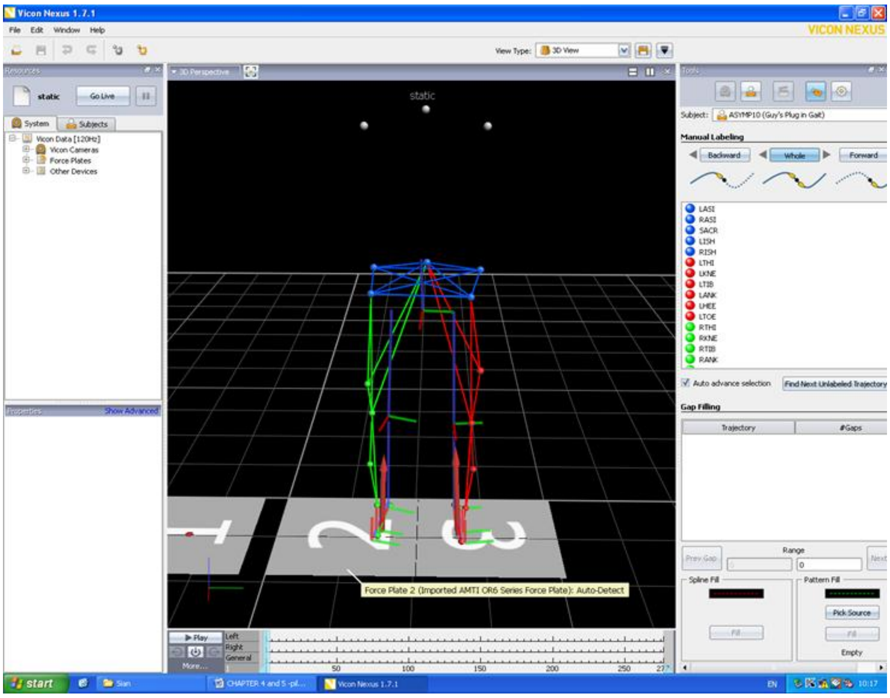
A static data capture was performed with all markers *in situ*, under barefoot and shod conditions. The participant was instructed to stand with feet on neighbouring force plates for the static capture, with arms folded. The markers in the static calibration trial were labelled (Figure 6.14) and Vicon's 'static plug in gait' model procedure was applied. This procedure determined lower limb joint centres from the anthropometric data and marker locations (Figure 6.15). Static trials were used to calculate particular offsets for the computation of ankle angles that were used in the modelling of trials collected subsequently. For barefoot trials, ankle offsets were calculated with the assumption that feet were plantar-grade. For shod trials, plantarflexion offsets were determined from the relative heights of the heel and toe markers. This calibration formed the basis of the Plug-in-Gait (PiG) routine that calculated kinematics and kinetics for the remaining trials in that session.

<u>Figure 6.14 Labelling of retro-reflective markers in Nexus</u>



Blue dots represent the five pelvic markers, red dots represent left lower limb markers, green dots represent right lower limb markers, white dots represent markers awaiting labelling, red vertical arrows represent ground reaction force vectors.

Figure 6.15 Application of Vicon's 'static plug in gait' model procedure



Blue dots represent the five pelvic markers, red dots represent left lower limb markers, green dots represent right lower limb markers. Vertical blue lines with short perpendicular red and green lines represent orthogonal reference frames for the underlying body segments.

6.10.3.3 Labelling of standing and gait trials

Following processing of the static trial, individual standing and gait trials were processed in Nexus. Three-dimension trajectories were reconstructed from the raw video trials shown in Figure 6.2 and labelled as shown in Figure 6.14. Gaps in the trajectories were inspected and filled using inbuilt commands in Nexus either by interpolation for small gaps or by copying the pattern of an adjacent trajectory if the gaps were large. If trials could not be filled without including obvious errors in the marker trajectory the trial was abandoned.

6.10.3.4 Filtering marker trajectories

The motion of the skin during gait can result in trajectory noise when markers are captured in three dimensional space. This artefact is normally minimised by the use of a digital low pass filter such as the Woltring cross-validatory quitic spline routine (Woltring, 1986). The Woltring filter is incorporated into the Vicon system. A Woltring system with mean standard error 10mm^2 was selected.

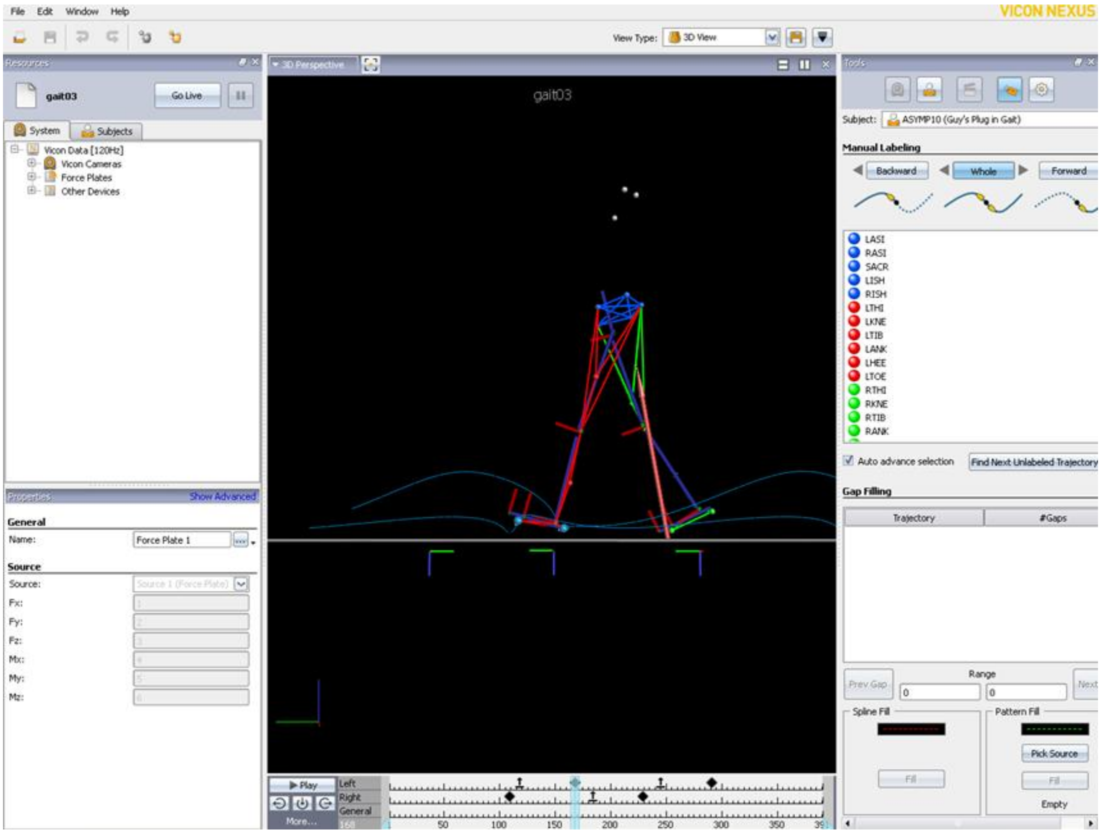
6.10.3.5 Processing standing and gait trials

Calculation of motion at the centres of each underlying joint was carried out via the PiG software model provided in the Vicon Nexus application that enables data to be processed; GRFs captured in three planes by a line of three AMTI force plates were integrated with kinematic data to calculate joint moments and powers using inverse dynamics. Kinetic parameters were normalised to body height to enable comparison between participants.

6.10.3.6 Gait cycle events

Gait cycle events of heel strike and toe off were defined in Nexus to facilitate the calculation of spatio-temporal parameters. These events were derived from force plate data when the participant had achieved a complete stride of the foot on the force plate without contacting the force plate with the contralateral foot *(6.10.2.1, p134)*. Figure 6.16 shows the labelling of heel strike and toe off events. A threshold of 10 Newtons was used to determine the points of heel strike and toe off. Trials without force plate data, or where force plate data were contaminated were defined by observation of the patterns of the heel and forefoot trajectories to determine gait cycle events (Figure 6.16). An error analysis of the two different methods employed to define the phases of gait demonstrated that this was a robust approach (*11.30, p309*).

Figure 6.16 Inspection of heel and forefoot trajectories to determine gait cycle events in the absence of force plate data

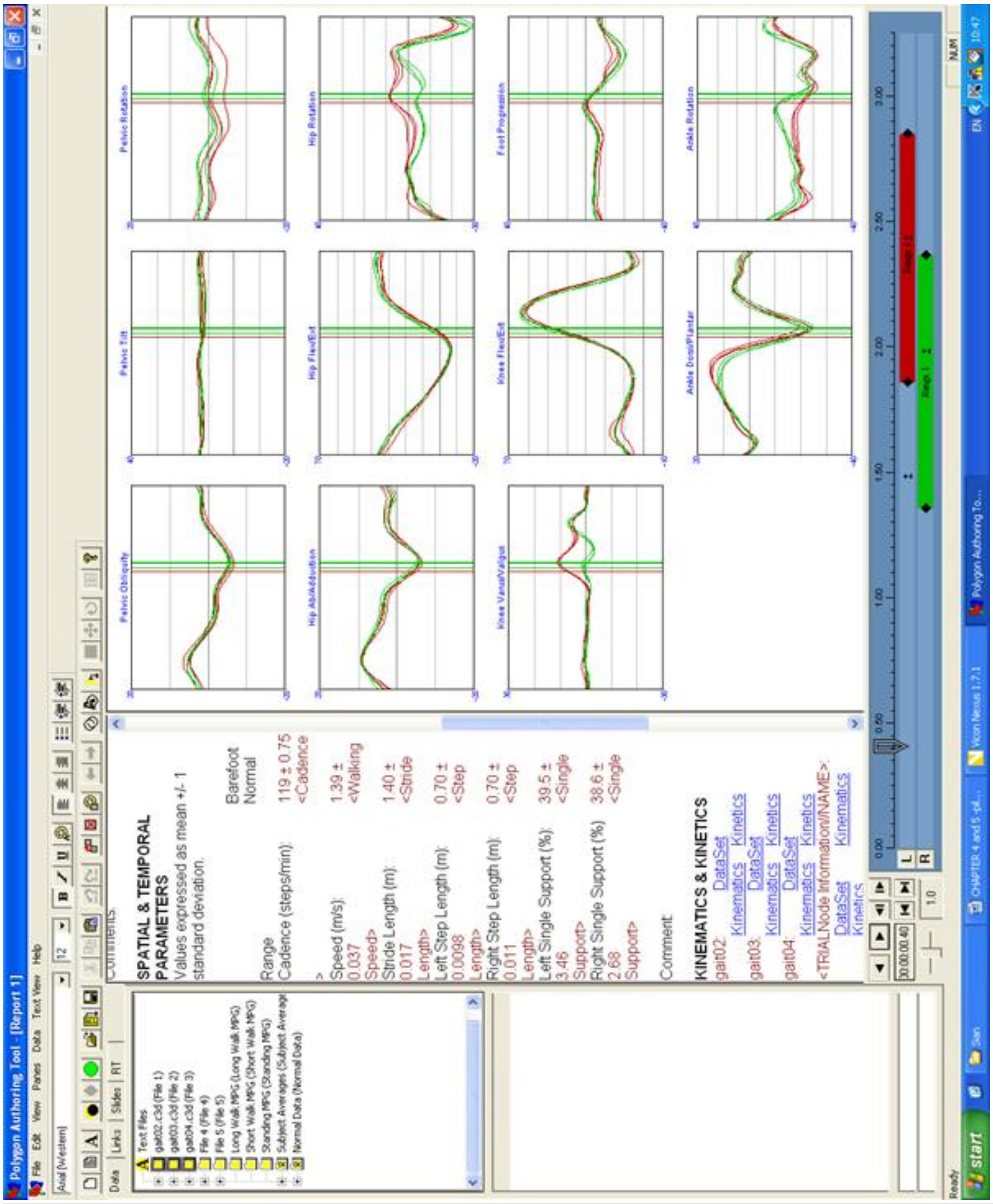


Blue curves represent left heel and toe movements through gait cycle. Participant captured walking from right to left side of screen. Red dots and red linking lines represent the left leg, green dots and green linking lines represent the right leg. Plug-in-gait model visible as shown in Figure 6.15. Bar directly below model indicates heel strike (diamond) and toe-off (upward arrow) for left (top row) and right (middle row) lower limbs.

6.10.3.7 Extraction of spatio-temporal, kinetic and kinematic gait data

Data was inspected using Polygon (Version 3.1) (Vicon Motion Systems, Oxford, UK) to identify artefacts in the computed kinematic and kinetic data. For example, it was used to identify and correct knee varus artefacts during swing – a common artefact observed in the data that may be caused by the misalignment of the thigh markers. The spatio-temporal, kinematic and kinetic data for each trial were then exported to Microsoft Excel (Microsoft, Reading, UK) using a macro routine in Polygon. An average was obtained for each participant for each limb for spatio-temporal parameters, and kinetic and kinematic data. Figure 6.17 demonstrates the visualisation of trials in Polygon. Table 6.4 lists the spatio-temporal, kinematic and kinetic key points exported from Polygon over the gait cycle.

Figure 6.17 Visualisation of joint motion in the software application Vicon Polygon



Legend for graphs:

Top row (left to right): Pelvic obliquity; Pelvic tilt; Pelvic rotation

Second row (left to right): Hip abduction/adduction; Hip flexion/extension; Hip rotation

Third row (left to right): Knee varus/valgus; Knee flexion/extension; Foot progression

Bottom row (left to right): Ankle dorsiflexion/plantarflexion; Ankle rotation

Green joint motion lines on graphs represent right lower limb

Red joint motion lines on graphs represent left lower limb

Y-axis represents joint angle. X-axis represents percent of gait cycle starting with heel strike X/Y interface

Table 6.4 Parameters extracted from Polygon by Excel macro

Parameter	Description	Units of measurement
Spatio-temporal		
Cadence	Number of steps taken in one minute	Steps/minute
Gait velocity	Distance covered over time	Metres/second
Stride length	Distance covered from heel strike of one limb to heel strike of the same limb	Metres
Kinematic		
Hip	Peak hip flexion	Degrees
	Peak hip extension	
	Range of hip movement in the sagittal plane	
Knee	Peak knee flexion during first half of stance	
Kinetic		
Moments	Peak hip flexor moment	Nmm/kg
	Peak hip extensor moment	

Legend: kg = kilograms, Nm = Newton millimetres

6.10.3.8 Extraction of centre of pressure parameters from standing trials

Centre of pressure parameter data for each trial were exported to Microsoft Excel using a macro routine written in Visual Basic for Applications. This programme read force plate data from each trial (contained within a c3d file – industry standard format) using c3dServer (Motion Lab Systems, 2012). The centre of pressure variables were calculated from extracted force plate moment and force data. The equations computed are presented in *6.11 (p142).* Descriptions of the variables assessed are presented in Table 6.5.

Table 6.5 Description of the postural control parameters assessed

Variable	Description	Units of measurement
CoP $_{RMSE\ AP}$	The root-mean squared error of the centre of pressure in the antero-posterior direction where error refers to the distance between the centre of pressure and the current value of the centre of pressure	Millimetres
CoP $_{VEL\ AP}$	The total distance travelled by the centre of pressure in the antero-posterior direction divided by the time taken	Millimetres/ second
Hip-Ankle Postural Control Index	Root-mean squared error (RMSE), a measure of deviation from a signal mean, was calculated for the hip flexor/extensor moment and the ankle plantarflexor/dorsiflexor moment. The ratio of these two variables was used to calculate the index.	-

Increase in CoP parameters represent a decrease in postural stability, a decrease in a parameter represents improved postural stability.

6.11 Outcome measures

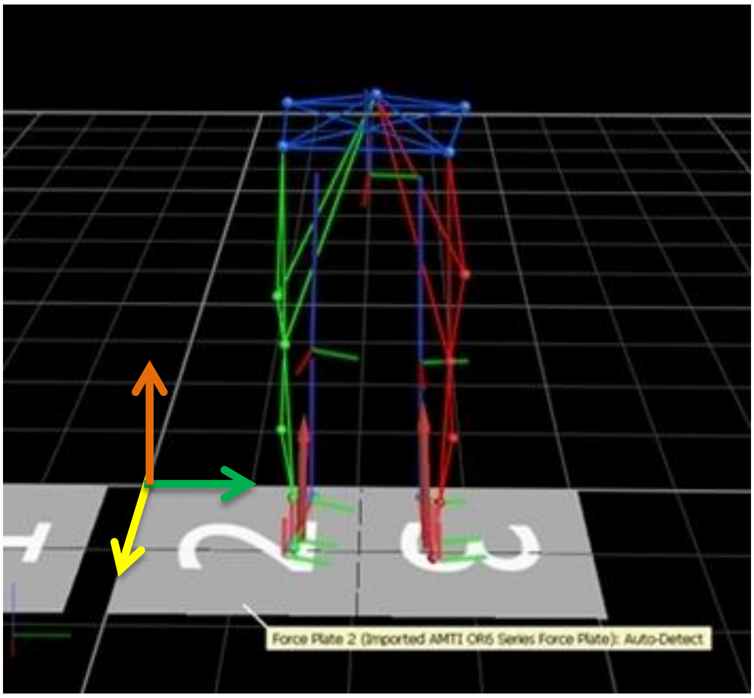
6.11.1 Centre of pressure parameters

Centre of pressure excursions are typically computed to assess postural stability. A systematic review, investigating the reliability and assessment protocols of CoP measures (Ruhe et al., 2010), published subsequently to the design of the current study protocol, reinforced the appropriateness of the selection of outcome measures chosen. From thirty-two studies assessed, no single measure of CoP appeared significantly more reliable than any other (Ruhe et al., 2010). Mean CoP velocity, however, consistently demonstrated acceptable reliability values hence was considered the most reliable CoP parameter (Ruhe et al., 2010). It is recommended to include a distance parameter (e.g. mean displacement) as well as a time-distance parameter (e.g. mean velocity) to gain an alternative description of the CoP excursion. Therefore, in the current study the root mean squared error of the CoP displacement in the anterior posterior direction, and mean CoP velocity in the antero-posterior direction were selected as appropriate outcome measures.

6.11.2 Centre of pressure calculations

Centre of pressure (CoP) calculations were made from the output from two force plates inset in the laboratory floor. Figure 6.18 demonstrates the *x, y* and *z* axes of the force plates.

Figure 6.18 Force plate axes



Yellow arrow represents the *x*-axis; green arrow, the *y*-axis; and orange arrow, the *z*-axis.

The x-coordinate of the CoP was calculated under each limb from the moments and forces produced by each plate with respect to the origin of the laboratory space, as follows:

$$x_{CoPl\_i} = \frac{-M_{yl\_i}}{F_{zl\_i}} + plate\ origin_{xl}$$

$$x_{CoPr\_i} = \frac{-M_{yr\_i}}{F_{zr\_i}} + plate\ origin_{xr}$$

where x_{CoPl_i}, x_{CoPr_i} are x- coordinates of the CoP under the left and right feet at time point *i*, and M_{yl_i}, M_{yr_i}, F_{zl_i}, F_{zr_i} are directional components of the moments and forces acting on the body from each forceplate. These coordinates are expressed relative to the global coordinates of the laboratory space by a translation between the origin of the forceplate and the origin of the laboratory ($plate\ origin_{xl}, plate\ origin_{xr}$).

The x-coordinate of the CoP of the whole body was calculated by multiplying the x-coordinate of the CoP for each limb by the fraction of the total vertical force (F_z) acting through that limb, and adding the two terms together, as follows:

$$x_{CoP\_i} = x_{CoPl\_i} * \left(\frac{F_{zl\_i}}{F_{zl\_i} + F_{zr\_i}}\right) + x_{CoPr\_i} * \left(\frac{F_{zr\_i}}{F_{zl\_i} + F_{zr\_i}}\right)$$

where x_{CoP_i} is the x-coordinate of the CoP of the whole body.

6.11.2.1 Calculation of the root mean squared error of the centre of pressure in the antero-posterior direction ($CoP_{RMSE\ AP}$)

The root mean squared error of the CoP in the antero-posterior direction (*x*-direction) is given by:

$$CoP_{RMSE\_AP} = \sqrt{\sum_{i}^{N} \frac{\left(x_{CoP\_i} - \overline{x_{CoP\_i}}\right)^2}{N}}$$

where $\overline{x_{CoP\_i}}$ is the mean position of the x-coordinate of the CoP, and *N* is the number of time points in the trial.

6.11.2.2 Calculation of centre of pressure velocity in the antero-posterior direction ($CoP_{VEL\ AP}$)

The mean velocity of the CoP in the antero-posterior direction (*x*-direction) is given by:

$$CoP_{VEL\_AP} = \sum_{i} \frac{\left|x_{CoP\_i} - x_{CoP\_i-1}\right|}{N} * f_s$$

where f_s is the data sampling frequency.

6.11.3 Postural strategy

Previous research has suggested that those with CLBP present with different hip and ankle strategies to people without back pain during more challenging standing conditions, such as with eyes closed on a compliant surface (Brumagne et al., 2008; Byl and Sinnott, 1991; Mok et al., 2004). These conclusions, regarding postural strategy were obtained from various approaches to calculating both hip and ankle strategies including; displacement of CoP data (Brumagne et al., 2008; Mok et al., 2004); horizontal shear force (Mok et al., 2004); and from visual inspection of the location of the fulcrum of body sway (Byl and Sinnott, 1991).

Although a variation in methods for interpreting the dominant postural control strategy in LBP participants exists, there is no agreement between studies as to a gold standard approach. It is usual to utilise a combination of hip and ankle strategies when maintaining posture (Horak and Nashner, 1986), however, few studies appear to consider a ratio of hip to ankle strategy in order to determining dominance of one strategy over another. Previous research (Brumagne et al., 2008) utilized a ratio approach to determine 'relative proprioceptive weighting' whereby the CoP displacement during mechanical vibration to the calf muscle was divided by the summation of both CoP displacement during mechanical vibration of the calf muscle and CoP displacement during mechanical vibration of the lumbar multifidus muscle. However, the validity of this approach in providing hip and ankle strategy data is unknown.

In the current study, the magnitude of fluctuation in joint moment was calculated to inform the contribution of each joint to the control of standing posture in the antero-posterior direction. When standing, increased fluctuation (standard deviation) in a joint moment implies an increased contribution from that joint to maintain postural stability (Winter, 2009). A greater moment fluctuation at the hip indicates an increase in hip strategy. Similarly, an increase in fluctuation values at the ankle represents an increase in ankle strategy.

6.11.3.1 Calculation of the hip to ankle strategy ratio

To calculate the Hip to ankle postural control index (*HAPCI*) it was necessary to calculate the root mean squared error of the hip extensor/flexor moment (Hm_{RMSE}) and the ankle plantarflexor/dorsiflexor moment (Am_{RMSE}) over the course of the standing trial, as follows:

$$Hm_{RMSE} = \sqrt{\sum_{i}^{N} \frac{\left(Hm_{fe\_i} - \overline{Hm_{fe}}\right)^2}{N}}$$

$$Am_{RMSE} = \sqrt{\sum_{i}^{N} \frac{\left(Am_{fe\_i} - \overline{Am_{fe}}\right)^2}{N}}$$

Where Hm_{fe_i}, Am_{fe_i} are the hip and ankle flexor/extensor moment at time point *i*, and $\overline{Hm_{fe}}, \overline{Am_{fe}}$ are the mean hip and ankle flexor/extensor moments over the trial.

To calculate the *HAPCI*, the root mean squared error of the hip extensor/flexor moment (Hm_{RMSE}) was divided by the root mean squared error of the ankle plantarflexor/dorsiflexor moment (Am_{RMSE}), as follows:

$$HAPCI = \frac{Hm_{RMSE}}{Am_{RMSE}}$$

6.11.3.2 Justification for the statistical analysis chosen to analyse data in the biomechanical studies

As described in *4.3.5 (p50),* an independent t-test is an appropriate statistical test to analyse the difference in mean values between two groups, when participants in each group are different, and where the assumption of normality is met (the variances of populations are similar and scores are independent) (Field, 2009). When assumptions of normality are not met, and data were non-parametric, the Mann-Whitney test will be chosen as the appropriate method to statistically analyse the difference in mean values between groups (Field, 2009).

A paired t-test will be used to analyse the difference in mean values from two samples of data from the same group of participants when assumptions of normality are met, and data are measured at least at the interval level (Field, 2009). When data do not meet these criteria the Wilcoxon signed rank test will be used as the appropriate method to statistically analyse the difference in mean values between the two samples (Field, 2009).

Justification for using the Chi square test and analysis of variance have been described in *4.3.5 (p50)*. A multivariate analysis of variance (MANOVA) is also conducted in the biomechanical studies. This is a type of ANOVA used when there is more than one outcome variable under investigation, and takes account of any relationship between the variables (Field, 2009). To assess postural control, measures of CoP velocity and CoP displacement were analysed. The MANOVA is chosen as an appropriate method to statistically analyse whether groups differed across a combination of postural control parameters, as opposed to a single CoP parameter.

7 The effect of footwear on balance and postural control in standing in chronic low back pain

7.1 Chapter summary

This study investigated the immediate, short term (six weeks) and long term (six month) effects of rocker sole and flat sole shoes on postural control and the relationship between the hip and ankle strategy in standing in those with chronic low back pain (CLBP). Four standing conditions with varying levels of postural challenge were assessed, whilst barefoot and whilst wearing study shoes. Although wearing rocker sole shoes introduced greater postural instability when standing compared to flat sole shoes, no difference between groups were observed in barefoot balance parameters, or the barefoot ratio of hip to ankle strategy at any follow-up point. This indicated that wearing both shoe types had a similar influence on barefoot postural control in standing in the short and long term. Neither shoe type appeared to offer a detectable long term training effect to the postural control system from the balance measures assessed.

7.2 Introduction

Differences in the postural control of standing have been reported between people with CLBP and asymptomatic individuals (Byl and Sinnott, 1991; Della Volpe et al., 2006; Luoto et al., 1996; Mientjes and Frank, 1999; Mok et al., 2004; Moseley and Hodges, 2005; Takala et al., 1997b). During more challenging standing conditions people with CLBP have demonstrated increased centre of pressure (CoP) displacements and velocities, thought to indicate a reduced ability to maintain postural stability. Furthermore, although under stable standing conditions people with and without CLBP both favour the ankle strategy to maintain postural control (Horak and Nashner, 1986), during more challenging conditions, people with CLBP continue to favour the ankle strategy whereas asymptomatic individuals favour a hip strategy (Brumagne et al., 2008; Mok et al., 2004), suggested as the more appropriate strategy to maintain postural control (Horak and Nashner, 1986). Although evidence for these conclusions is not strong, poor postural control has been proposed as an underpinning mechanisms in the presence and recurrent nature of CLBP (Brumagne et al., 2008; Mok et al., 2004).

Rehabilitation with proprioceptive or balance training has demonstrated clinical benefits to other regions of the body with postural control deficits (Fitzgerald et al., 2000; Tropp and Askling, 1988). It has been suggested that proprioceptive or balance training may also be effective in the treatment of CLBP (Johanssen et al., 1995). A manufacturer of rocker sole shoes (Masai Barefoot Technology Limited) has suggested that the unstable sole in their footwear can help to improve balance through 'sensorimotor' training and hence, 'benefit' functional daily activities (Masai Barefoot Technology GB Ltd, 2011). When standing in rocker sole shoes, greater centre of pressure (CoP) displacements have been reported compared to when wearing a flat sole shoe (Nigg et al., 2006b). A larger displacement of the (CoP) is interpreted as increased instability. If rocker sole shoes do serve as an effective balance training device by increasing postural instability compared to flat sole shoes they may offer clinical benefit to those with CLBP and impaired postural control as demonstrated in other lower limb dysfunctions treated with proprioceptive rehabilitation programmes (Fitzgerald et al., 2000; Tropp and Askling, 1988). This study therefore investigated the following study hypotheses:

Null hypothesis (H_0):

H_0 1 There will be no difference in postural stability when standing in rocker sole shoes or flat sole shoes.

H_0 2: Both shoe groups will demonstrate no change in postural stability in the antero-posterior direction during barefoot standing at six weeks or six months compared to baseline.

H_0 3: There will be no change in the hip to ankle postural control index in either group during more challenging barefoot standing conditions at six weeks and six months when compared to baseline.

Alternative hypothesis (H_1):

H_1 1 Standing in rocker sole shoes will promote a greater postural instability than standing in flat sole shoes in the antero-posterior direction compared to barefoot standing.

H_1 2: Both shoe groups will demonstrate an improvement in postural stability in the antero-posterior direction during barefoot standing at 6 weeks and 6 months, with the rocker shoe group demonstrating a greater improvement.

H_1 3: Both groups will demonstrate an increase in the hip to ankle postural control index (indicating an increased proportional input from the hip strategy) during more challenging barefoot standing conditions at six weeks and six months in both study groups, with the rocker shoe group demonstrating a greater increase.

7.3 Methods

7.3.1 Design

This prospective randomised controlled trial with repeated measures at baseline, six weeks and six months recruited participants from the main clinical study *(Chapter 5, p61).* Cross-sectional and longitudinal analysis of data were conducted. The chief investigator (C.I.) remained blind to subject group allocation.

7.3.2 Ethical approval

Ethical approval for the study was gained through the Outer North London Research Ethics Committee (REC: 10/H0724/7) *(11.31, p312).*

7.3.3 Participant recruitment

Participants were recruited into this study as described in *6.7 (p118).*

7.3.4 Interventions

All assessments were conducted in the 'One Small Step' gait laboratory, Guy's hospital. On arrival to the laboratory, and under supervision of the C.I., participants completed the trial consent form *(11.32, p315),* the Roland Morris Disability questionnaire *(11.3, p225)* and were asked to report a numerical rating score for their low back pain.

Participants changed into shorts and vest top, and removed their shoes and socks. Anthropometric measurements *(6.9.2, p123)* from each participant were recorded by the C.I. and co-researcher, Dr Adam Shortland (PhD supervisor and Clinical Manager of the One Small Step Gait Laboratory). Retro-reflective markers were placed on the appropriate bony landmarks *(6.9.3, p127)* by Dr Shortland followed by a short data capture *(6.10.3.2, p136).*

7.3.4.1 Static balance test procedure - barefoot

Each participant stood barefoot, their feet approximately pelvis width apart with their left and right feet on adjacent force plates. No additional instructions were given to the participants regarding how to place their feet on the force plates in order to allow them to assume their habitual standing posture. A brief familiarisation period of wearing the markers and standing on the force plates, prior to the data acquisition, allowed the subjects to become accustomed to the equipment and testing procedure. Participants were assessed under four standing conditions, each condition assessed over three 40 second trials:

(1) firm ground with eyes open

(2) firm ground with eyes closed

(3) compliant ground (foam cushion) with eyes open

(4) compliant ground (foam cushion) with eyes closed

Each participant received the same instructions at the start of each trial:

“When I say ‘Go’ I want you to stand and maintain your balance until you hear the instruction to rest. Each trial will last for 40 seconds. Focus on the red sticker on the tripod ahead of you. Keep your arms relaxed by your sides.”

A rest period of approximately 20 seconds occurred between each 40 second trial. A test was invalidated if the participant: 1) moved their foot position on the force plate during the test; 2) changed their arm starting position or; 3) opened their eyes during an eyes-closed task. Sufficient trials were performed to enable three valid sets of data to be recorded.

The C.I. advised subjects that if they felt particularly unstable during the trials they should open their eyes and/or step off the foam cushion or force plate. Between trials on the compliant surface the C.I. checked that each foam cushion maintained its position on the force plate.

7.3.4.2 Static balance test procedure - shod

In order to maintain blinding of the C.I. to participant footwear group allocation, the C.I. vacated the gait laboratory. The co-researcher then continued with the shod assessment. Foot markers were relocated to the study footwear *(6.9.3.1, p130)*. Following a short data capture and whilst wearing study shoes, the study protocol described in *7.3.4.1 (p151)* was repeated by the participants.

7.3.5 Outcome measures

The following outcome measures were assessed at baseline, six weeks and six months:

- Postural stability (root mean squared error and velocity of the centre of pressure in the antero-posterior direction: CoP $_{RMSE\ AP}$ and CoP $_{VEL\ AP}$ respectively *[6.11.2, p143])*
- Postural strategy (Hip to ankle postural control index *[6.11.3, p145])*
- Disability (Roland Morris Disability questionnaire)
- Pain (Numerical rating score)

7.3.6 Sample size

Recruitment into the biomechanical study commenced in June 2010 and ended at the same time as recruitment into the main clinical study (November 2010). Twenty CLBP participants were recruited from the remaining 55 participants consenting into the main clinical study *(Chapter 5, p61)*. A sample size calculation to determine appropriate power was not conducted due to the lack of reporting of minimal clinically important difference data for the primary outcome measures (CoP parameters).

7.3.7 Data analysis

Baseline data are presented in order that results may be compared with other trials and to judge the effectiveness of randomisation. Distributions were checked to see if normal distributions had been met, if this was not the case, non-parametric tests were performed.
Mixed ANOVAs were conducted with one within-subject factor (assessment time point) and one between group factor (footwear type) to compare the influence of footwear type over time, and one within groups factor (standing condition) and one between group factor (footwear type) to compare baseline data between groups. ANOVA utilised data from

participants with complete data sets (rocker sole shoe group n = 11, flat sole shoe group n = 5 for long term follow-up; rocker sole shoe group n = 13, flat sole shoe group n = 7 for baseline comparisons and immediate effect of footwear). The alpha level for determining statistical significance was set at 0.05.The reasoning underpinning choice of statistical tests has been described in *6.11.3.2 (p146).*

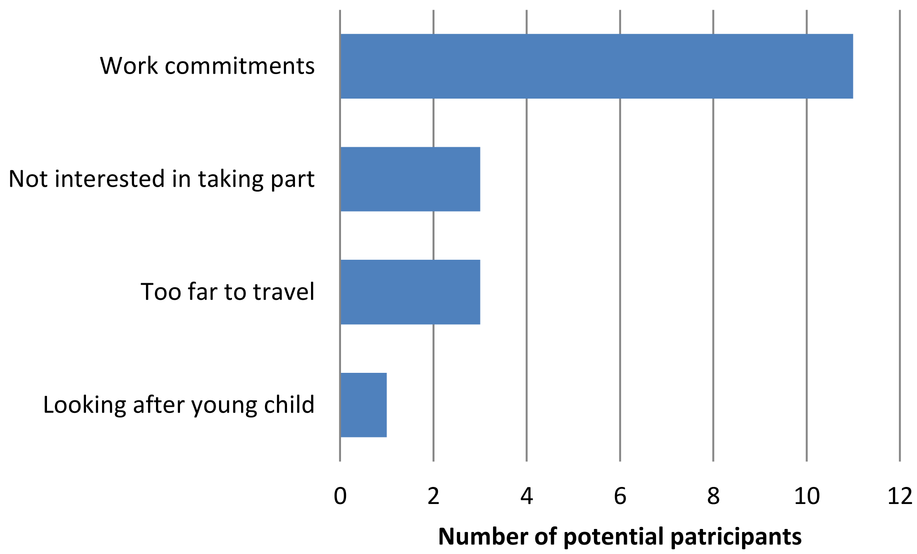
Data were analysed using IBM SPSS 20.0.0 (IBM, New York). Results are presented as means (standard deviations (SD)) unless otherwise stated.

7.4 Results

7.4.1 Recruitment

During the recruitment period (June 2010 - November 2010) 38 patients in the main clinical study (REC reference number: 09/H0706/4) showed interest in participating in the biomechanical study. Following telephone conversation or face-to-face meeting with the C.I., 18 of the potential participants reported that they were not able to take part in the biomechanical trial. Reasons for the non-participation of these potential participants are presented in Figure 7.1. Twenty participants were consented into the study.

Figure 7.1 Reasons for non-participation of participants



7.4.2 Participant baseline characteristics

Baseline study demographic data and self-reported pain and disability outcome measures for the 20 participants are presented in Table 7.1. Of the 20 participants recruited seven had been randomized to receive the flat sole shoe and 13 to receive the rocker sole shoe. There were no differences between groups for any of the baseline demographic data, pain or disability outcome measures. At baseline those in the flat sole shoe group tended to be heavier and report increased disability than those in the rocker sole shoe group.

Table 7.1. Participant demographic data

	Flat sole shoe group (n=7)	Rocker sole shoe group (n=13)	P - value
Gender : Male	3 (42.9 %)*	6 (46.2 %)*	0.89†
: Female	4 (57.1 %)*	7 (53.8 %)*	
Age (years)	37.9 (13.0)	42.6 (12.5)	0.43
Weight (kg)	82.4 (22.0)	70.3 (11.3)	0.12
Height (cm)	173.8 (7.3)	173.5 (9.5)	0.95
Roland Morris Disability Questionnaire (0-24; 0=best)	7.9 (1.8)	5.7 (3.3)	0.13
Numerical rating score for pain (0-10; 0=best)	6.3 (1.5)	5.7 (1.7)	0.48

Summary measures represent means (SD) or *numbers (percentages). Data analysed with independent t-test or Chi-squared test†.

Baseline barefoot CoP parameters are presented in Table 7.2. No differences were detected in change in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ between the flat sole and rocker sole shoe groups for any of the four standing conditions ($F(3,51) = 0.41$, $p = 0.75$, $\eta^2 = 0.02$ and $F(1.14,19.31) = 0.74$, $p = 0.69$ $\eta^2 = 0.01$).

Table 7.2 Barefoot antero-posterior centre of pressure parameters at baseline

Standing condition	Group	CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]
Eyes open no cushion	Flat sole shoe	4.89 (2.27)	6.93 (2.66)
	Rocker sole shoe	4.51 (1.85)	7.07 (1.97)
Eyes closed no cushion	Flat sole shoe	5.73 (2.36)	8.21 (2.17)
	Rocker sole shoe	4.23 (1.29)	8.24 (2.60)
Eyes open cushion	Flat sole shoe	10.36 (2.50)	16.31 (3.53)
	Rocker sole shoe	8.84 (2.67)	14.94 (3.28)
Eyes closed cushion	Flat sole shoe	12.01 (2.49)	27.34 (11.89)
	Rocker sole shoe	11.49 (2.67)	25.91 (9.13)

Summary measures represent means (SD). RMSE: root mean squared error. VEL: velocity. AP: antero-posterior.

Tables 7.3 presents baseline hip:ankle postural control indexes for the different standing conditions. No difference was observed in change in hip to ankle strategy between groups for any of the standing conditions assessed for the left or right lower limb ($F(4.87,77.97)=0.96$, $p=0.44$, $\eta^2=0.06$ and $F(4.82,77.03)=1.44$, $p=0.22$, $\eta^2=0.08$ respectively).

Table 7.3 Baseline sagittal plane hip to ankle postural control index during standing

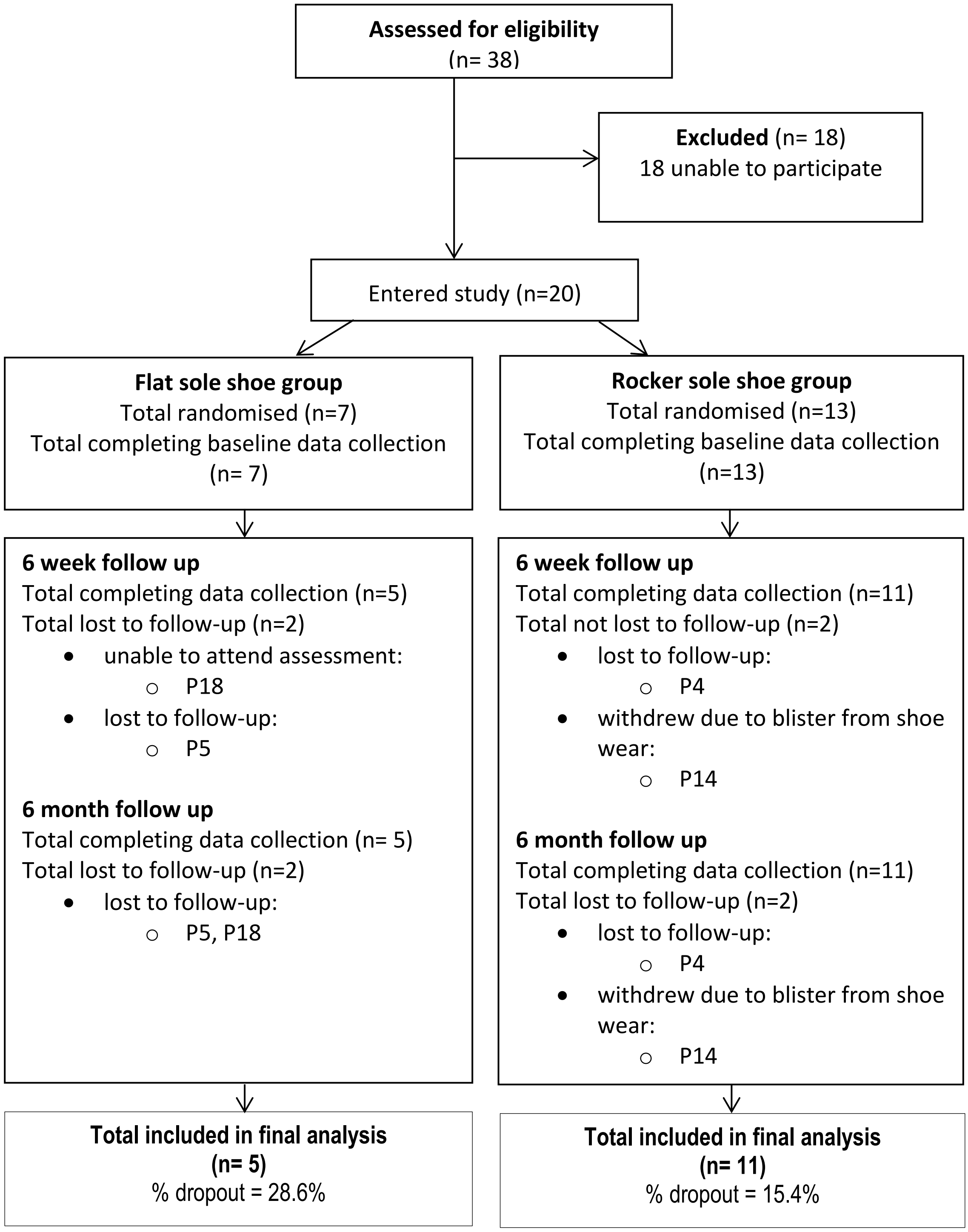
		Hip : ankle postural control index	
		Left	Right
Eyes open no cushion	Flat sole shoe	0.31 (0.11)	0.37 (0.12)
	Rocker sole shoe	0.31 (0.09)	0.35 (0.13)
Eyes closed no cushion	Flat sole shoe	0.31 (0.07)	0.41 (0.12)
	Rocker sole shoe	0.33 (0.08)	0.36 (0.13)
Eyes open cushion	Flat sole shoe	0.28 (0.10)	0.32 (0.11)
	Rocker sole shoe	0.28 (0.08)	0.24 (0.07)
Eyes closed cushion	Flat sole shoe	0.30 (0.08)	0.33 (0.09)
	Rocker sole shoe	0.25 (0.09)	0.41 (0.27)

Summary measures represent means (SD).

7.4.3 Participant retention and attrition

Sixteen (80%) participants were reassessed at six weeks and at 12 months. Two participants were lost to follow-up from each group. Participant retention and attrition during the study are presented Figure 7.2.

Figure 7.2 Flow of participants through trial



Participant identification codes are reported as ‘P’ = participant, followed by a number identifying the ‘nth’ participant entering the trial.

7.4.3.1 Comparison of centre of pressure parameters when standing barefoot and standing shod

Standing in a rocker sole shoe, with eyes-open on firm ground, resulted in a mean increase in CoP $_{RMSE\ AP}$ of 6.62mm (146.8%, $p < 0.01$) when compared to standing barefoot (Table 7.4). Standing, eyes-open on firm ground, in rocker sole shoes resulted in a mean increase in CoP $_{VEL\ AP}$ of 8.10mm/s (114.4%, $p < 0.01$) when compared to standing barefoot. There was no difference in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ when standing barefoot compared to standing in flat sole shoes (Table 7.4).

Table 7.4 Sagittal plane centre of pressure parameters during barefoot and shod standing, with eyes open on firm ground

	Flat sole shoe group (n=7)		Rocker sole shoe group (n=13)	
	CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]	CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]
Barefoot	4.89 (2.27)	6.93 (2.66)	4.51 (1.85)	7.07 (1.97)
Shod	5.76 (2.33)	7.44 (1.83)	11.13 (3.00)	15.16 (3.34)
Increase in displacement when shod	0.87 (2.04) 17.8%	0.51 (1.56) 12.2%	6.62 (2.94)* 146.8%	8.10 (3.38)* 114.4%

Summary measures represent means (SD) or percentages where indicated (%).* Significant difference within groups between barefoot and shoe conditions (paired t-test, $p < 0.01$). RMSE: root mean squared error, VEL: velocity, AP: antero-posterior.

7.4.3.2 Longitudinal comparison of clinical outcome in biomechanical study sample and main clinical study

Comparison of change in disability for each shoe group between the biomechanical study and the main clinical study demonstrated similar reductions in disability and pain at six weeks and six month follow-ups (disability: rocker sole group $F(2, 106) = 0.20$, $p = 0.82$, $\eta^2 = 0.001$; flat sole shoe, $F(1.53, 73.4) = 0.24$, $p = 0.73$, $\eta^2 = 0.01$; pain: rocker sole shoe, $F(1.70,90.10)=0.01$, $p=0.99$, $\eta^2 <0.01$, and flat sole shoe group, $F(2,96) = 1.04$, $p = 0.36$, η^2 0.02) (Table 7.5).This indicates that for each shoe group the biomechanical study sample was representative of the main study sample for measures of disability and pain.

<u>Table 7.5 Disability and pain outcomes for biomechanical study participants and main clinical study participants</u>

Outcome measure	Assessment point	Flat sole shoe		Rocker sole shoe	
		Main study	Biomechanics study	Main study	Biomechanics study
Change in disability score	Baseline to 6 weeks	-3.2 (-4.4 to -1.9)	-4.4 (-6.8 to -2.0)	-2.2 (-3.2 to -1.2)	-1.7 (-3.6 to 0.2)
	Baseline to 6 months	-4.2 (-5.7 to -2.7)	-5.2 (-7.2 to -3.2)	-2.3 (-3.4 to -1.1)	-1.6 (-4.1 to 1.0)
Change in pain score	Baseline to 6 weeks	-1.9 (-2.7 to -1.1)	-1.3 (-3.3 to 0.7)	-2.0 (-2.7 to -1.2)	-1.95 (-3.4 to -0.5)
	Baseline to 6 months	-2.6 (-3.4 to -1.8)	-3.6 (-5.9 to -1.3)	-2.4 (-3.2 to -1.6)	-2.45 (-4.0 to -0.9)

Summary measures represent mean (SD).

7.4.3.3 Influence of long term shoe wear on barefoot sagittal plane centre of pressure parameters

Neither the rocker sole nor the flat sole shoe group demonstrated change in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ when assessed barefoot, with eyes closed on compliant ground, at any follow-up point (rocker sole shoe group $F(2, 20) = 2.81$, $p = 0.08$, $\eta^2 = 0.22$ and $F(2, 20) = 1.96$, $p = 0.17$, $\eta^2 = 0.16$ respectively; flat sole shoe group $F(2, 6) = 2.22$, $p = 0.81$, $\eta^2 = 0.07$ and $F(2, 6) = 0.42$, $p = 0.67$, $\eta^2 = 0.12$ respectively) (Table 7.6). Furthermore, there were no differences between groups in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ at any follow-up point during the most challenging standing condition ($F(2,26) = 0.51$, $p = 0.61$, $\eta^2 = 0.04$ and $F(2,26)=0.96$, $p=0.40$, $\eta^2 =0.07$). A trend for a reduction in velocity was observed in the rocker sole shoe group at six weeks and six months when compared to baseline.

Table 7.6 Change in barefoot centre of pressure parameters during standing, eyes closed on foam cushion at reassessment points

	Centre of pressure parameter	Assessment			P-value
		Baseline	6 weeks	6 months	
Flat sole shoe group	CoP $_{RMSE\ AP}$ [mm]	10.97 (1.60)	10.74 (2.50)	10.44 (2.49)	0.81
	CoP $_{VEL\ AP}$ [mm/s]	33.73 (8.43)	32.31 (10.94)	35.77 (16.84)	0.67
Rocker sole shoe group	CoP $_{RMSE\ AP}$ [mm]	11.31 (2.88)	10.09 (2.72)	10.46 (3.22)	0.08
	CoP $_{VEL\ AP}$ [mm/s]	26.03 (9.98)	22.50 (6.91)	22.45 (7.59)	0.17

Summary measures represent means (SD).

No difference in COP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ were found for the three other less challenging standing conditions assessed (eyes open, no cushion; eyes closed, no cushion; and eyes open, with cushion) within each shoe group or between shoe groups at any follow-up point.

7.4.3.4 Influence of long term shoe wear on postural control assessed when shod.

When standing in study shoes, with eyes open on firm ground, no significant differences where observed in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ for either shoe group at any reassessment point (rocker sole shoe group: $F(2, 20) = 1.29$, $p = 0.30$, $\eta^2 = 0.11$, and $F(2, 20) = 2.06$, $p = 0.15$, $\eta^2 = 0.17$ respectively; flat sole shoe group: $F(2, 8) = 0.77$, $p = 0.50$, $\eta^2 = 0.16$, $F(2, 8) = 1.62$, $p = 0.26$, $\eta^2 = 0.30$). Furthermore, whilst wearing study shoes there were no differences between groups in change in CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ at any reassessment point ($F(2,28) = 1.17$, $p = 0.33$, $\eta^2 = 0.08$, and $F(2,28) = 2.37$, $p = 0.11$, $\eta^2 = 0.14$ respectively) (Table 7.7).

Table 7.7 Change over time in antero-posterior centre of pressure parameters during shod standing, eyes open on firm ground

	Centre of pressure parameter	Assessment			P - value
		Baseline	6 weeks	6 months	
Flat sole shoe group	CoP $_{RMSE\ AP}$ [mm]	5.38 (1.52)	6.21 (3.00)	5.49 (2.23)	0.50
	CoP $_{VEL\ AP}$ [mm/s]	7.84 (2.06)	8.63 (2.24)	9.05 (3.02)	0.26
Rocker sole shoe group	CoP $_{RMSE\ AP}$ [mm]	10.50 (2.82)	9.82 (2.77)	11.30 (3.83)	0.30
	CoP $_{VEL\ AP}$ [mm/s]	14.96 (2.79)	13.95 (3.40)	13.25 (3.11)	0.15

Summary measures represent means (SD). P – value: repeated measures ANOVA

7.4.3.5 Comparison of hip and ankle strategies when barefoot and shod

A greater increase in ankle strategy from barefoot to shod was observed in the rocker sole compared to the flat sole shoe group (right ankle: $F(1, 18)=10.40$, $p=0.01$, $\eta^2= 0.37$; and the left ankle: $F(1,18) = 8.51$, $p=0.01$, $\eta^2= 0.32$). Changes in hip strategy from barefoot to shod were not different between groups (left hip: $F(1.18)=0.12$, $p=0.74$, $\eta^2= 0.01$; right hip: $F(1,18)=1.50$, $p=0.24$, $\eta^2 =0.08$). Figure 7.3 demonstrates that hip strategy is minimally influenced by rocker sole shoes compared to when barefoot.

The hip:ankle postural control index was reduced in the rocker sole shoe group, when shod compared to barefoot (Table 7.8). Figure 7.3 indicates that the reduced index results from an increase in ankle strategy. In the flat sole shoe group, barefoot and shod standing resulted in similar Hip: ankle postural control indexes (Table 7.8), indicating change in hip and ankle strategy between barefoot and shod standing was directly proportional.

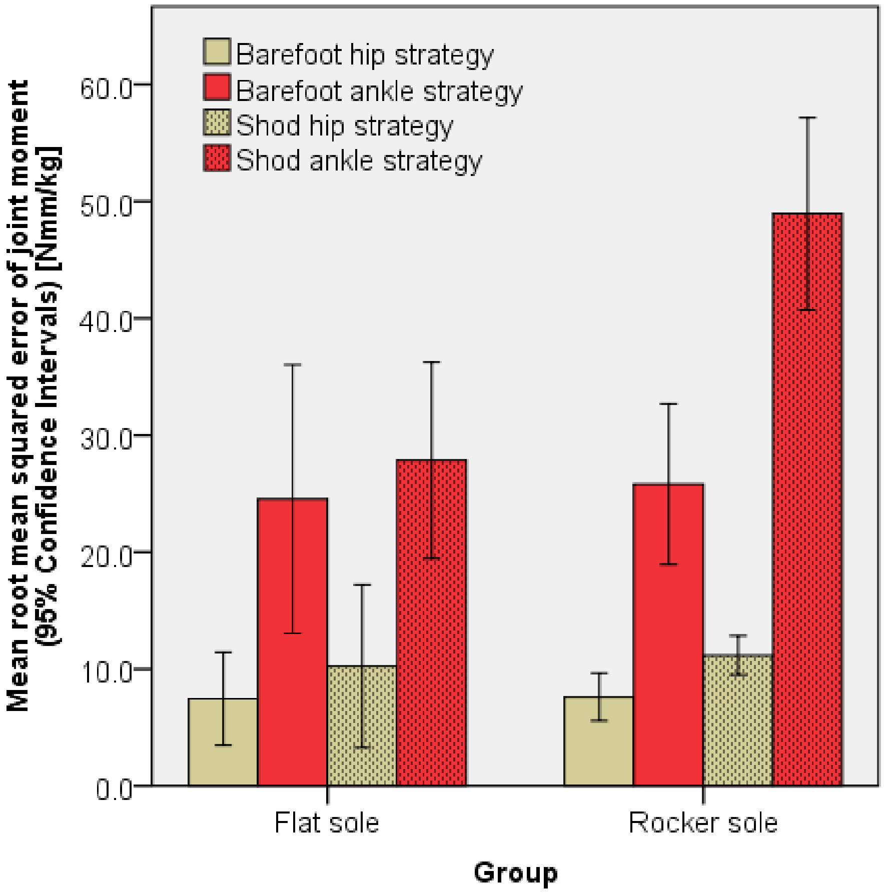
There were no differences between groups in hip to ankle postural control index from barefoot to shod ($F(1, 18) = 2.83$, $p=0.10$, $\eta^2 = 0.14$ for the left, and $F(1,18)=3.46$, $p=0.08$, $\eta^2= 0.16$ for the right side) (Table 7.8).

Table 7.8 Hip to ankle postural control index when barefoot and shod

	Flat sole shoe group		Rocker sole shoe group	
	Left	Right	Left	Right
Barefoot	0.31 (0.11)	0.37 (0.12)	0.31 (0.09)	0.35 (0.13)
Shod	0.37 (0.23)	0.39 (0.16)	0.24 (0.07)*	0.26 (0.08)*

Summary measures represent mean (SD). * represents p < 0.05 within shoe groups, paired t-test).

Figure 7.3 Hip and ankle strategy during barefoot and shod standing (for the left lower limb)



7.4.3.6 Influence of long term shoe wear on postural strategy in barefoot standing

There were no differences, within groups or between groups, in the hip: ankle postural control index at baseline, six weeks and six months when assessed in standing with eyes open on firm ground or during more challenging trial conditions (eyes closed standing on foam) (Table 7.9).

Table 7.9 Ratio of hip to ankle strategy in the maintenance of an upright standing posture

		Flat sole shoe group		Rocker sole shoe group		P - value	
		Left	Right	Left	Right	Left	Right
Eyes open no cushion	Baseline	0.29 (0.08)	0.40 (0.13)	0.33 (0.08)	0.37 (0.13)	0.38	0.15
	6 weeks	0.33 (0.09)	0.56 (0.26)	0.35 (0.11)	0.38 (0.14)		
	6 months	0.35 (0.13)	0.38 (0.16)	0.33 (0.09)	0.30 (0.07)		
Eyes closed cushion	Baseline	0.34 (0.06)	0.38 (0.04)	0.26 (0.10)	0.28 (0.08)	0.60	0.18
	6 weeks	0.34 (0.05)	0.37 (0.05)	0.25 (0.07)	0.25 (0.04)		
	6 months	0.38 (0.08)	0.32 (0.07)	0.26 (0.10)	0.28 (0.04)		

Summary measures represent means (SD). A value of 0 would represent a 100% contribution from the ankle strategy. Analysis: repeated measures and mixed ANOVA's.

7.5 Discussion

Rocker sole shoes provided a less stable surface to stand on than flat sole shoes. Furthermore, the increase in ankle strategy from standing barefoot to shod was significantly greater in the rocker sole shoe than in the flat sole shoe. Change in hip strategy between barefoot and shod standing was similar between groups. This suggests that whilst wearing the rocker sole shoes the ankle strategy, and not the hip strategy appears to be the primary strategy for maintenance of postural stability in people with CLBP. Although these findings suggest that rocker sole shoes may be more likely to influence postural control strategies there was no difference in barefoot postural strategy ratios or CoP parameters within or between groups during barefoot trials at 6 weeks or 6 months for stable or unstable standing conditions. Furthermore, there was no change from baseline in CoP parameters in the rocker sole shoe group when shod at six weeks and six months. These findings suggest that adaptation of the postural control system did not occur following long term wear of rocker sole shoes. The lack of change in CoP and postural strategy outcomes suggests that wearing rocker sole shoes did not appear to cause a training effect capable of influencing postural stabilising systems in those with CLBP.

7.5.1 Outcomes

7.5.1.1 Antero-posterior centre of pressure parameters.

Baseline values of antero-posterior CoP parameters were compared to available results from CLBP trials investigating the same outcome measures under similar study protocols. The current study demonstrated similar CoP parameters between shoe groups at baseline, however, when compared to the findings of other studies the current study demonstrated increased postural stability during more stable standing (Brumagne et al., 2004; Brumagne et al., 2008; Della Volpe et al., 2006), and reduced postural stability during more challenging standing (Brumagne et al., 2004; Brumagne et al., 2008; Lafond et al., 2009).

These differences may be due to a number of methodological differences, namely: calculating the mean from three or more trials (as conducted in the current study) produces more reliable data than that obtained from one trial (Ruhe et al., 2011a) as conducted by Brumage et al. (2004; 2008) and Lafond et al. (2009) - only using one repetition may have reduced the reliability of data collected in these other studies; greater trial durations provide more reliable data (Ruhe et al., 2011a) – a minimal trial duration time by Della Volpe et al. (2006) may have reduced data reliability. Further factors have been demonstrated to influence outcome measure data include participant age (postural stability reduces with age (Doyle et al., 2004; Era and Heikkinen, 1985; Hageman et al., 1995; Hasselkus and Shambes, 1975)), weight (Chiari et al., ; Hue et al., 2007), height (increased height may reduce postural stability) (Chiari et al., ; Hue et al., 2007) and gender (due to the fact that males are generally taller than females) (Hageman et al., 1995). Brumage et al (2004; 2008) recruited only young adults, two studies did not report participant gender (Brumagne et al., 2004; Lafond et al., 2009), and although mean height of participants was similar across studies, Brumage et al (2008) reported reduced mean weight of participants compared to the other studies. All studies, including the current study, have investigated small sample sizes (between 10 and 21 participants) – which may increase the risk of statistical error. The consistent increase in CoP parameters from stable to more challenging standing conditions in the current study concurred with findings of other trials (Brumagne et al., 2008; Mok et al., 2004).

Reduction in a CoP parameter is interpreted as an improvement in postural stability (Ruhe et al., 2011a). It was hypothesised that due to the increased proprioceptive input from wearing the rocker shoes (Masai Barefoot Technology GB Ltd, 2011) a greater reduction in barefoot and shod postural excursion may occur at reassessment in the rocker sole compared to the flat sole group. However, neither group demonstrated a significant change in CoP parameters at six weeks or six months. This lack of change suggests that the rocker sole footwear, reported by the manufacturing company to be a 'sensorimotor training device' which 'can help to improve balance' (Masai Barefoot Technology GB Ltd, 2011) either i.) provided an additional postural challenge, however this type of challenge does not affect long term improvements in sensori-motor function, ii.) did not influence balance sufficiently for a training effect (classified by a change in CoP parameters) to occur, or iii.) did influence potential proprioceptive deficits, however, improvements were not detected possibly due to: insensitivity of outcome measures investigated; a type two error resulting from an underpowered sample; or poor data reliability due to methodological faults. These explanations are discussed in greater detail below.

The first explanation, suggesting that the increased postural challenge from rocker sole shoes does not influence long term improvements in sensori-motor function compared to wearing flat sole shoes, concurs with the findings of other studies (Nigg et al., 2009; Nigg et al., 2006a). Nigg et al. investigated the influence of rocker sole footwear on balance in golfers with LBP (Nigg et al., 2009) and in people with knee osteoarthritis (Nigg et al., 2006a). In support of the current study findings, Nigg et al. concluded that no differences in balance performance were detected between the intervention (rocker sole group) or control groups (normal shoes) at six weeks in the low back pain study and at twelve weeks in the knee study. The current study adds to Nigg et al's conclusions by demonstrating that longer term use of rocker sole shoes has no further influence on postural stability.

The second explanation, suggests that if a greater postural challenge had been elicited, a training effect (identified by a significant change in CoP parameters) may have occurred. When compared to standing barefoot, the rocker shoes demonstrated more than a 100% increase in the CoP parameters assessed. Introducing additional postural challenge in an attempt to increase the CoP parameters further may not only be unsafe or impractical in a CLBP population, but may also, in the absence of evidence to support a relationship between increased postural challenge and change in CoP parameters or clinical change, be inappropriate.

The third explanation suggests that the null hypothesis was incorrectly accepted and that study conclusions are incorrect. Several factors may contribute to this explanation. The sample may be underpowered because of poor reliability of the outcome variables and because of an insensitivity to detect genuine changes in postural control. The reliability of the outcome variables would be improved by increasing the duration of the trials and by introducing more trials. However, of the numerous CoP parameters regularly reported in research assessing postural stability, the two parameters chosen in the current study have been reported as highly reliable (Ruhe et al., 2011a).

Change in CoP parameters have been suggested as an appropriate outcome measure to detect clinical change (Ruhe et al., 2011b). In the current study, differences in mean CoP $_{RMSE\ AP}$ at six months during challenging standing conditions were -0.52 and 0.85 mm for the different shoe types and change in mean CoP $_{VEL\ AP}$ were 2.04 and -3.58 mm/s for the different shoe types. To the authors knowledge, measurements of the standard error of CoP parameters, during challenging standing conditions, are yet to be reported in the literature for people with CLBP, however, the figures reported above are less than the reported standard errors from reliability studies conducted in elderly participants (who also demonstrate poor postural stability) (2010). Changes in CoP parameters following an intervention may be too small to reliably determine whether change in postural stability has occurred.

Regarding the sensitivity of the CoP parameters, the current thesis demonstrates clinically important significant reductions in disability and pain at follow-up, but no change in postural parameters. This thesis and the findings of (Kuukkanen and Malkia, 2000) suggest that CoP parameters may be insensitive to real changes in postural control or that there may be no significant changes in control. If the latter, the use of any mechanical indices as outcome measures would be inappropriate; if the former, alternative mechanical outcome measures need to be developed and tested.

7.5.1.2 Hip to ankle strategy ratio

The control of standing balance is thought to be strongly linked to the relationship between hip and ankle strategies (Horak and Nashner, 1986). Due to a paucity in the reporting of hip to ankle strategy ratios, as calculated in the current study (from standard deviations of joint moments, obtained from two force plates by an inverse dynamics method), it was not possible for the baseline data from this current study to be compared with other CLBP populations. Furthermore, lack of research reporting long term changes in postural strategy following an intervention does not allow comparison of the current study findings to other research.

Neither footwear group demonstrated a change in barefoot hip to ankle postural control index at any reassessment point when compared to baseline. This suggests that the reductions in pain and disability observed in the current study did not influence, or result from a change in the hip to ankle ratio (Horak and Nashner, 1986). In people with CLBP, during more challenging conditions, the ankle strategy is reported to be the favoured strategy (Brumagne et al., 2008; Mok et al., 2004) whereas in asymptomatic individuals the hip strategy is favoured (Brumagne et al., 2008; Mok et al., 2004) and suggested as a more appropriate strategy to maintain postural control (Horak and Nashner, 1986). In the current study it was hypothesised that, due to the unstable surface of the rocker sole shoe, a ‘sensorimotor’ training effect may influence or ‘normalise’ dominance of the hip over the ankle strategy during more challenging postural standing conditions. However, wearing the rocker sole shoes had a similar minimal influence on the hip strategy as the flat sole shoes, hence is unlikely to have a greater or lesser influence on postural strategy than a flat sole shoe.

7.5.2 Clinical implications

Long term use of rocker sole shoes or flat sole shoes in addition to attendance to a four week LBP exercise group do not appear to influence barefoot postural control (as determined by CoP parameters and the ratio of hip to ankle strategy) during standing in those with CLBP.

Changes in CoP parameter measures are suggested to correlate with postural control impairment in humans (Ruhe et al., 2010). Although clinical improvement in pain and disability are noted in this sample, change in CoP parameters did not occur, raising doubt to the theory that treatment approaches directed towards influencing or 'normalising' altered CoP parameters may result in clinical improvements in those with CLBP. Predicting presence and severity of CLBP using CoP parameters alone cannot currently be advised.

7.6 Conclusions

This is the first RCT with long term (six month) follow-up comparing the influence of rocker sole and flat sole shoes on CoP parameters and postural strategy ratios in a chronic pain population.

- Standing in a rocker sole shoe reduced postural stability compared to standing barefoot whereas standing in a flat sole shoe did not influence postural stability.
- At baseline, standing in a rocker sole shoe reduced the hip to ankle postural control index compared to barefoot. This resulted from a greater proportional increase in ankle strategy, not the hip strategy.
- Neither shoe group demonstrated change from baseline in the hip to ankle postural control index or CoP parameters during stable or more challenging standing conditions when barefoot or shod when reassessed at six weeks and six months. This suggest that long term use of rocker sole or flat sole shoes in those with CLBP do not appear to influence postural stability.
- This study questions the belief that sensorimotor rehabilitation, especially when delivered in standing using rocker sole shoes, will influence postural control in people with CLBP.
- It remains unclear as to whether CoP parameters are appropriate measures to imply presence and severity of CLBP or clinical change in those with CLBP.
- It is unclear what effect either shoe type may have on CoP parameters and postural control strategies in people with more severe CLBP or if worn for greater than six months.

8 The effect of footwear on kinetic, kinematic and spatio-temporal parameters during gait in people with chronic low back pain

8.1 Chapter summary

This study investigated the immediate and long term (six month) influence of rocker sole and flat sole shoes on kinetic, kinematic and spatio-temporal parameters during gait in people with chronic low back pain (CLBP). Parameters of gait were assessed whilst walking barefoot and shod. Although walking in both shoe types compared to barefoot gait resulted in mild alterations to participants gait parameters at baseline, neither shoe group demonstrated significant differences in barefoot gait at six months. This suggests that neither shoe type provided a long term training effect capable of influencing the kinetic, kinematic or spatio-temporal parameters assessed during barefoot gait.

8.2 Introduction

Differences in gait have been identified between people with and without CLBP (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007; Vogt et al., 2003; Vogt et al., 2001); people with CLBP demonstrating a reduced self-selected walking speed (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007), stride time (Vogt et al., 2003; Vogt et al., 2001), stride length (Al-Obaidi et al., 2003; Keefe and Hill, 1985), and range of hip movement (Vogt et al., 2003). Researchers have proposed that these gait changes may be an attempt by the individual to reduce pain by reducing ground reaction forces at heel strike (Voloshin and Wosk, 1982), excessive muscle activity or joint movement (Ahern et al., 1988). Alternatively, differences may be a result of altered proprioceptive feedback (Mazzocchio et al., 2001) or psychological factors associated with low back pain, such as anxiety, fear avoidance, hyper-vigilance and catastrophising (Leeuw et al., 2007). Psychological factors may lead to adaptation of normal physical activities, such as fast walking, due to the fear of an increase in pain. Although gait alterations may initially be protective, such alterations may induce mechanical problems in the longer term, for example, a slower walking speed has been shown to produce longer periods of loading on the lumbar spine during gait (Callaghan et al., 1999), which may be detrimental to spinal structures in the long term, whereas more cyclic, shorter periods of loading, thought to be less detrimental, occur during faster walking (Callaghan et al., 1999). Variations in gait in people with compared to asymptomatic individuals have been proposed as an underpinning mechanism in the presence and recurrent nature of CLBP. For this theory to be accepted, change in gait parameters (for example, an increase in gait velocity or stride length) would be expected in the presence of reduced pain or disability.

Different footwear types have demonstrated an ability to influence gait. Shod compared to barefoot walking increases stride length and velocity (Demura et al., 2012; Keenan et al., 2011; Lythgo et al., 2009). Wearing shoes increases the mass and the distribution of mass of the limb. This alters the dynamics of walking in a similar way to how the dynamics of a Grandfather clock pendulum is altered by moving the attached mass. In the current study, the rocker sole shoes are twice the mass of the flat sole shoe and have the thicker sole. Therefore, at baseline, it was expected that the rocker sole shoes would result in a greater increase in stride length, lower cadence and greater walking velocity than the flat sole shoes when compared to barefoot walking. However, this theory challenges previous research reporting reduced gait velocity (Romkes et al., 2006; Taniguchi et al., 2012) and stride length (Romkes et al., 2006) in rocker sole compared to flat sole shoes in asymptomatic individuals.

A longer stride length is likely to be related to a greater excursion at the hip since angular changes at the hip are more likely to have a greater influence on step length than changes at the more distal joints. A greater hip range of movement was therefore expected for shod walking, with a greater increase in range for the rocker sole compared to the flat sole group. However, this theory challenges previous research reporting similar (Demura and Demura, Epub ahead of print), or decreased (New and Pearce, 2007; Romkes et al., 2006; Taniguchi et al., 2012) hip range during gait in rocker sole shoes compared to flat sole trainers.

Peak hip extensor moments occur immediately after initial contact of the foot with the ground to decrease hip flexion and trunk rotation; peak hip flexor moments occur as the foot leaves the ground, to swing the leg forward (Apkarian et al., 1989). Due to the proposed increases in stride length, walking speed and hip range of movement whilst shod, hip joint moments are likely to increase during shod compared to barefoot gait, and by a greater amount in the rocker sole shoes. If either footwear has a long term influence on the musculoskeletal system, increased hip moments may be demonstrated during barefoot gait at long term follow up compared to baseline.

Transient force peaks, the sharp increases in ground reaction force detected immediately after heel strike, have been implicated as a potential cause and aggravator of LBP (Light et al., 1980; Voloshin and Wosk, 1982). Whittle et al (1999) stated that the body has two natural defences against potential damage from these transient force peaks : appropriate joint alignment during the first half of stance and the presence of viscoelastic materials in the heel pad and joints. A cushioning effect from footwear may further assist in reducing external forces reaching the spine, or may influence lower quadrant joint angles during the stance phase of the gait cycle, increasing shock attenuation. A greater peak flexion angle during the first half of stance, suggested to increase shock attenuation of ground reaction forces (Whittle, 1999), has been observed whilst walking in rocker sole shoes compared to flat sole shoes (Taniguchi et al., 2012). Furthermore, a reduced incidence of transient force peaks when walking in rocker sole shoes compared to flat sole shoes has been demonstrated in asymptomatic individuals (Vernon et al., 2004). Therefore, if increased forces passing through the body contribute to CLBP, the rocker sole shoe may contribute to improved shock attenuation. If rocker sole shoes improve shock attenuation, and if such forces contribute to CLBP, a concomitant reduction in pain and disability, and hence increases in gait speed, stride length, and hip range of movement may be expected in the long term.

Due to the paucity of evidence available and hence lack of understanding of the biomechanical response from the body from wearing rocker sole shoes the following hypotheses are proposed only tentatively:

Null hypotheses (H_0):

Immediate effects

H_0 1 Shod and barefoot walking will demonstrate similar stride lengths and self-selected walking speed.

H_0 2 Shod and barefoot walking will demonstrate similar hip range of movement.

H_0 3 Shod and barefoot walking will demonstrate similar incidence of transient force peaks associated with heel strike.

H_0 4 Shod and barefoot walking will demonstrate similar peak knee flexion angle during the first half of stance.

Long term effects

H_0 5 During barefoot walking at six months, both shoe groups will demonstrate similar self-selected walking speed and stride length when compared to baseline

H_0 6 During barefoot walking at six months, both shoe groups will demonstrate a similar magnitude of hip moment when compared to baseline.

H_0 7 During barefoot walking at six months, both shoe groups will demonstrate similar hip range of movement when compared to baseline.

Alternative hypotheses (H_1):

Immediate effects

H_1 1 Shod walking will demonstrate an increase in stride length and self-selected walking speed compared to walking barefoot, with a greater increase in the rocker sole shoe group compared to the flat sole shoe group.

H_1 2 Shod walking will demonstrate an increase in hip range of movement during gait when compared to walking barefoot, with a greater increase in the rocker sole shoe group compared to the flat sole shoe group.

H_1 3 Shod walking will demonstrate a decreased incidence of transient force peaks associated with heel strike compared to walking barefoot, with a greater decrease in the rocker sole shoe group compared to the flat sole shoe group.

H_1 4 Shod walking will demonstrate an increase in peak knee flexion angle during the first half of stance compared to walking barefoot, with a greater increase in the rocker sole shoe group compared to the flat sole shoe group.

Long term effects

H_1 5 During barefoot walking at six months, both groups will demonstrate an increase in self-selected walking speed and increase in stride length when compared to baseline. The rocker shoe group will demonstrate greater increases from baseline than the flat sole shoe group.

H_1 6 During barefoot walking at six months, both groups will demonstrate an increase in the magnitude of the hip moments when compared to baseline. The rocker shoe group will demonstrate greater changes from baseline than the flat sole shoe group.

H_1 7 During barefoot walking at six months, both groups will demonstrate an increase in hip range of movement when compared to baseline. The rocker shoe group will demonstrate a greater increase in hip range from baseline than the flat sole shoe group.

8.3 Methods

8.3.1 Design

This prospective randomised controlled trial with repeated measures at baseline and six months recruited participants from the main clinical study described in *Chapter 5 (p61).* The same participants taking part in the study described in *Chapter 7 (p148)* also participated in this study. Cross-sectional and longitudinal analysis of data was conducted. The chief investigator (C.I.) remained blind to participant group allocation.

8.3.2 Ethical approval

Ethical approval for the study was gained through the Outer North London Research Ethics Committee (REC: 10/H0724/7) *(11.31, p312).*

8.3.3 Participant recruitment

Recruitment of participants into this study is described in *6.7 (p118).*

8.3.4 Assessment

All assessments were conducted in the 'One Small Step' gait laboratory, Guy's hospital. This study occurred in conjunction with the study described in *Chapter 7 (p148)*. Study documentation forms had been completed, anthropometric measurements recorded and retro-reflective markers placed *(7.3.4, p150).*

8.3.4.1 Assessment of barefoot gait

Participants were asked to walk barefoot, at a pace that felt comfortable to them, from one end of the laboratory to the other, in a line which passed over the three force plates. Each participant received the same instructions:

"When I say go I want you to walk in a straight line to the marker at the other end of the room. Walk at a pace that feels comfortable to you."

Participants continued walking the length of the laboratory until the C.I. had observed three clear force plate strikes for each foot *(6.10.2.1, p134).*

8.3.4.2 Assessment of shod gait

The C.I. left the gait laboratory in order to remain blind to participant group allocation. The co-researcher (Dr Adam Shortland) continued with the footwear assessment. Foot markers were relocated to the study footwear *(6.9.3.1, p130).* The study protocol *(8.3.4.1, p176)* was repeated by the participants, whilst wearing their study footwear.

The co-researcher then removed all markers from the participant and from their shoes. Participants were informed that the double sided sticky tape used to attach the markers to the skin may leave a red mark on the skin for approximately one hour following marker removal. Participants were advised that this is normal and should not be of concern. Once participants had removed their study shoes and changed back into their normal clothing the C.I. was permitted to re-enter the laboratory.

At the end of the initial assessment the C.I. informed participants to start wearing their study shoes for a minimum of two hours per day (as instructed by the C.I. in their baseline assessment for the main clinical study, *[5.3.7.1, p75]*).

8.3.5 Outcome measures

The following outcome measures were assessed at baseline and 6 months:

- Self-selected walking speed [metres/second]
- Stride length [metres]
- Cadence [steps per minute]
- Hip range of movement [degrees]
- Peak knee flexion during the first half of stance [degrees]
- Hip moments [Newton millimetres/kilogram]

8.3.6 Sample size

Sample size is described in *7.3.6 (p152).*

8.3.7 Data analysis

All statistical tests were performed using SPSS statistical software (version 20.0) (IBM, New York). Paired t-tests, were applied to spatio-temporal parameters to determine change between walking barefoot and walking in study shoes. Independent t-tests for parametric data, or Mann-Whitney U-tests for non-parametric data, were applied to determine differences between groups. Long-term between group effects were assessed by mixed analysis of variance (ANOVA). The alpha level for determining statistical significance was 0.05. The reasoning underpinning choice of statistical test is presented in *6.11.3.2 (p146).*

8.4 Results

8.4.1 Recruitment

Recruitment is described in *7.4.1. (p153).*

8.4.2 Participant baseline characteristics

Demographic characteristics of participants at baseline are described in *7.4.2 (p154).* Baseline parameters of gait are presented in Table 8.1. No differences were observed between groups.

Table 8.1 Baseline barefoot spatio-temporal and kinematic outcome measures

	Rocker sole group (n=13)	Flat sole group (n=7)	P - value
Walking speed [metres/second]	1.28 (0.16)	1.20 (0.27)	0.36
Cadence [steps/minute]	114.30 (9.95)	108.97 (14.90)	0.35
Stride length [metres]	1.35 (0.13)	1.31 (0.14)	0.50
Left hip range of movement [degrees]	44.1 (4.8)	44.3 (5.1)	0.92
Right hip range of movement [degrees]	43.2 (4.5)	42.4 (4.7)	0.71

Summary measures represent mean (SD). P-values : Independent t-test

8.4.3 Participant retention and attrition

Participant retention and attrition is presented in *7.4.3 (p156).*

8.4.4 Spatio-temporal parameters

8.4.4.1 Immediate effects of footwear on spatio-temporal parameters

Both groups demonstrated an increase in walking speed and stride length during shod compared to barefoot gait. No differences were detected between groups for either parameter (walking speed, $F(1,18) = 2.72$, $p = 0.11$, $\eta^2 = 0.13$; stride length $F(1.18) = 2.74$, $p = 0.12$, $\eta^2 = 0.13$). Compared to walking barefoot, cadence reduced when walking in rocker sole shoes, but did not change when walking in flat sole shoes. There was no difference in cadence between groups when comparing barefoot and shod walking ($F(1,18) = 2.64$, $p = 0.12$, $\eta^2 = 0.13$) (Table 8.2).

Table 8.2 Immediate effects of footwear on spatio-temporal parameters of gait compared with barefoot gait

	Shoe group	Barefoot	Shod	P - value
Walking speed [metres/second]	Rocker	1.28 (0.16)	1.37 (0.10)$^{¥}$	0.11
	Flat	1.20 (0.27)	1.37(0.19)*	
Cadence [steps/minute]	Rocker	114.30 (9.95)	111.60 (9.1)$^{¥}$	0.12
	Flat	108.97 (14.90)	109.9 (10.30)	
Stride length [metres]	Rocker	1.35 (0.13)	1.48 (0.08)*	0.12
	Flat	1.31 (0.14)	1.49 (0.12)*	

Summary measures represent mean (SD). Within group differences between barefoot and shod are represented by ¥ $p < 0.05$, and * $p < 0.01$. P - value: between group mixed ANOVA

8.4.4.2 Long term effects of footwear on barefoot spatio-temporal parameters

No differences were detected in barefoot spatio-temporal parameters at six months compared to baseline from long term wear of either shoe type. Furthermore, no between group differences were detected in spatio-temporal parameters from long term shoe wear (walking speed: $F(1,14) = 1.83$, $p=0.20$, $\eta^2 = 0.12$; cadence, $F(1,14) = 2.82$, $p = 0.12$, $\eta^2 = 0.17$; stride length, $F(1,14) = 0.51$, $p = 0.49$. $\eta^2 = 0.04$) (Table 8.3).

Table 8.3 Barefoot spatio-temporal parameters of gait at baseline and 6 months

	Shoe group	Baseline	6 months	P - value
Walking speed [m/s]	Rocker	1.28 (0.17)	1.32 (0.16)	0.20
	Flat	1.20 (0.22)	1.18 (0.18)	
Cadence [steps/minute]	Rocker	113.77 (10.80)	115.86 (8.84)	0.12
	Flat	109.99 (9.57)	108.38 (5.58)	
Stride length [m]	Rocker	1.35 (0.13)	1.37 (0.15)	0.49
	Flat	1.30 (0.15)	1.30 (0.15)	

Summary measures represent mean (SD). P - value : between group mixed ANOVA

8.4.5 Kinematic parameters

8.4.5.1 Immediate effects of footwear on kinematic parameters

Walking in flat sole shoes increased sagittal hip range of movement compared to walking barefoot (left: $t(6) = -3.20$, $p = 0.02$; right: $t(6) = -4.29$, $p = 0.01$). There was a small increase in hip range when walking in rocker sole shoes for the right hip (right, $t(12)=-2.41$, $p = 0.03$; left, $t(12) =-1.48$, $p = 0.17$). The flat sole group demonstrated a greater increase in right hip range from barefoot to shod gait than the rocker sole group; there was no difference between groups for the change in left hip range (left hip: $F(1,18) = 2.32$, $p = 0.15$, $\eta^2 = 0.11$; right hip: $F(1,18) = 5.64$, $p = 0.03$, $\eta^2 = 0.24$) (Table 8.4).

Neither shoe type significantly altered peak knee flexion angle during the first half of stance compared to barefoot walking (rocker sole shoe, left: $t(12) = -1.17$, $p = 0.27$; right: $t(12) = -1.76$, $p = 0.10$, flat sole shoe, left: $t(6) = -2.12$, $p = 0.08$; right: $t(6) = -0.32$, $p = 0.76$). There were no between group differences in change in peak knee flexion angle, during the first half of stance, when mobilising shod compared to barefoot (left: $F(1,18)=1.93$, $p = 0.18$, $\eta^2 = 0.10$; right: $F(1,18) = 0.63$, $p = 0.63$, $\eta^2 = 0.01$).

Table 8.4 Immediate effect of footwear on kinematics of gait

Joint angle	Shoe group	Barefoot	Shod	P-value
Left hip range of movement [degrees]	Rocker	44.1 (4.8)	45.4 (4.0)	0.15
	Flat	44.3 (5.1)	47.8 (5.6)*	
Right hip range of movement [degrees]	Rocker	43.2 (4.5)	44.7 (4.1)*	0.03
	Flat	42.4 (4.7)	46.4 (4.7)*	
Peak left knee flexion during first half of stance	Rocker	19.2 (5.3)	21.2 (5.3)	0.18
	Flat	18.1 (6.9)	21.3 (7.5)	
Peak right knee flexion during first half of stance	Rocker	19.7 (4.9)	21.1 (4.6)	0.63
	Flat	18.1 (8.2)	18.7 (7.9)	

Summary measures represent mean (SD); *represents within group $p < 0.05$ (paired t-test). P - value: between group mixed ANOVA

8.4.5.2 Long term effects of footwear on barefoot kinematic parameters

There was no change in barefoot hip range of movement at six months compared to baseline for either shoe group (rocker sole shoe, left: $t(10) = -1.70$, $p = 0.12$; right: $t(10) = -0.93$, $p = 0.37$, flat sole shoe, left: $t(4) = -1.19$, $p = 0.30$; right: $t(4) = -1.55$, $p = 0.20$) indicating that long term use of either shoe type did not influence range of hip movement during barefoot gait (Table 8.5). Change in barefoot hip range of movement at six months compared to baseline was not significantly different between groups (left hip $F(1,14) <0.01$, $p = 0.97$, $\eta^2 <0.01$, right hip $F(1,14) = 1.27$, $p = 0.28$, $\eta^2 = 0.08$).

Table 8.5 Long term effect of footwear use on barefoot sagittal hip range of movement during gait

	Shoe group	Baseline	6 months	P-value
Left hip range of movement [degrees]	Rocker	43.7 (5.1)	45.4 (6.6)	0.97
	Flat	43.9 (2.5)	45.7 (3.3)	
Right hip range of movement [degrees]	Rocker	42.8 (4.6)	43.7 (5.8)	0.28
	Flat	42.8 (2.1)	46.0 (4.2)	

Summary measures represent mean (SD); analysis within-group: paired t-test; between group: mixed ANOVA.

8.4.6 Kinetic parameters

8.4.6.1 Immediate effect of footwear on transient force peaks

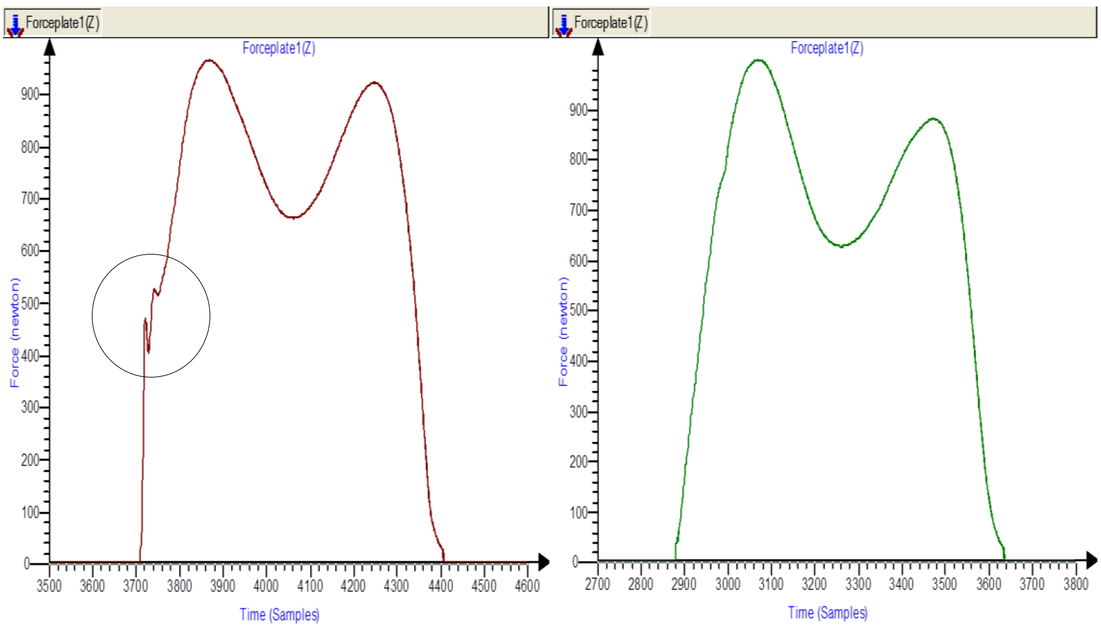
For both groups there was a reduction in the percentage of foot falls with transient force peaks when shod compared to barefoot (rocker sole shoe group: $z = -3.19$, $p <0.01$; flat sole shoe group $z = -2.02$, $p = 0.04$) (Table 8.6). There were no differences between groups in the percentage of foot falls with transient force peaks when barefoot ($U = 33.0$, $z = -1.01$, $p = 0.32$) or shod ($U = 33.5$, $z = -1.25$, $p=0.21$). Figure 8.1 and Figure 8.2 demonstrate the transient force peaks associated with heel strike during barefoot gait and the absence of such peaks during shod gait for the flat sole and rocker sole shoe group respectively.

Table 8.6 Immediate effect of footwear on transient force peaks at heel strike

	Shoe group	Barefoot	Shod
Incidence of transient force peaks [percent]	Rocker	73.2 (29.4)	5.8 (15.0)*
	Flat	56.9 (35.3)	14.3 (19.7)*

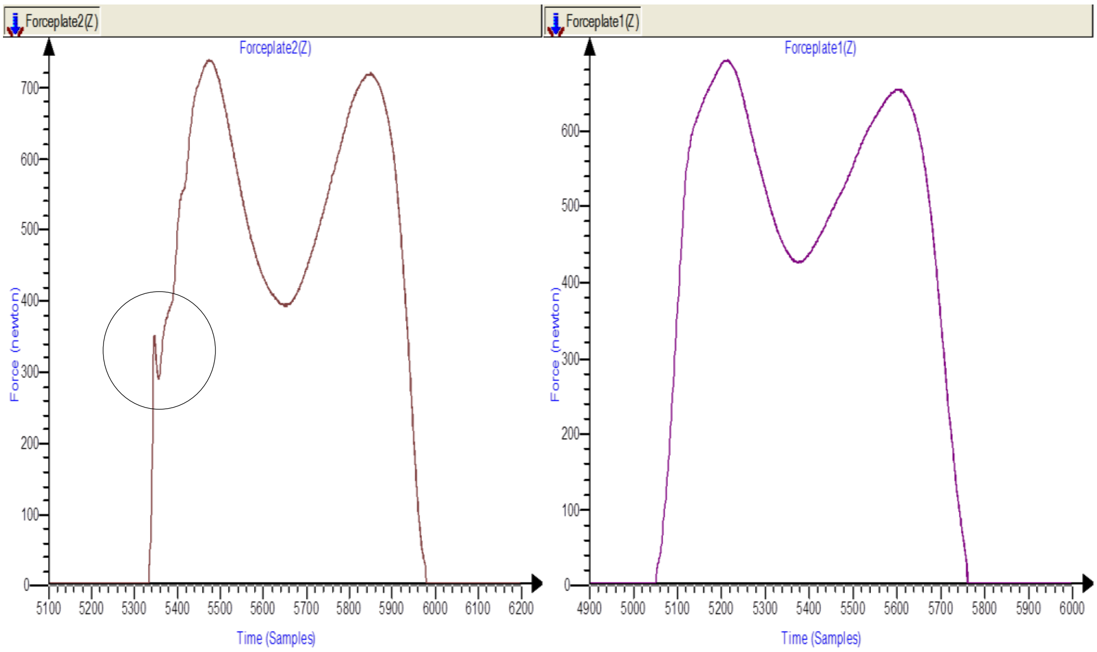
Summary measures represent mean percent of heel strikes with associated transient force peaks (SD). Within shoe group analysis: Wilcoxon signed rank, * represents p <0.05.

Figure 8.1 Flat sole shoe group: transient forces peaks associated with heel strike during barefoot and shod gait



Left hand graph: barefoot; right hand graph: flat sole shoes. Y-axis: vertical ground reaction force. X-axis: time. Transient force peak (highlighted by circle) visible during barefoot gait (data from participant 'Gait03').

Figure 8.2 Rocker sole shoe group: transient forces peaks associated with heel strike during barefoot and shod gait



Left hand graph: barefoot; right hand graph: flat sole shoes. Y-axis: vertical ground reaction force. X-axis: time. Transient force peak (highlighted by circle) visible during barefoot gait (data from participant number 'Gait010').

8.4.6.2 Long term effects of footwear on joint moments during barefoot gait

No differences were observed within groups for barefoot hip moment data from baseline to six months. Furthermore, no differences were observed between groups for change in barefoot hip moment data from baseline to six months (Left hip extensor $F(1,14) = 1.34$, $p = 0.27$, $\eta^2 = 0.09$; right hip extensor: $F(1,14) = 0.01$, $p = 0.91$, $\eta^2 < 0.01$; left hip flexor: $F(1,14) = 0.12$, $p = 0.74$, $\eta^2 = 0.01$; right hip flexor: $F(1,14) = 0.02$, $p = 0.89$, $\eta^2 < 0.01$). This indicates that long term use of either footwear did not influence hip flexor or extensor moments during barefoot gait (Table 8.7).

Table 8.7 Joint moments at baseline and six months during barefoot gait

Peak joint moment	Shoe group	Baseline [Nmm/kg]	6 months [Nmm/kg]	% difference	P - value
Left hip extensor	Rocker §	1025.35 (377.86)	1102.24 (513.79)	7.50	0.27
	Flat	733.76 (444.33)	490.72 (146.05)	-33.12	
Right hip extensor	Rocker §	1096.68 (409.26)	1023.64 (433.75)	-6.66	0.91
	Flat §	855.65 (640.08)	805.58 (406.70)	-5.85	
Left hip flexor	Rocker	-1107.47 (188.33)	-1157.98 (293.37)	4.56	0.74
	Flat	-1009.87 (125.22)	-1000.80 (145.63)	-0.90	
Right hip flexor	Rocker	-1004.24 (171.38)	-1005.77 (191.14)	0.15	0.89
	Flat	-878.03 (97.02)	-864.26 (198.97)	-1.57	

§ represents within group non-parametric Wilcoxon test for within group analysis, otherwise within groups paired t-test conducted. P - value: between group mixed ANOVA.

8.5 Discussion

Abnormal spatio-temporal, kinetic and kinematic parameters of gait have previously been suggested as factors associated with the presence and recurrence of CLBP. Findings from the current study suggest that although immediate differences between groups were demonstrated in some parameters when comparing barefoot to shod gait, rocker and flat sole shoes had no long term influence on specific kinetic, kinematic, and spatio-temporal parameters of barefoot gait. The lack of long term change in these parameters suggests that if proposed underpinning mechanisms such as gait speed (Callaghan et al., 1999), stride length (Al-Obaidi et al., 2003; Keefe and Hill, 1985) or transient force peaks (Light et al., 1980; Voloshin and Wosk, 1982) do contribute to the presence of CLBP it is unlikely that rocker sole shoes would provide any greater or lesser long term influence on these mechanisms or CLBP, than a flat sole shoe.

Walking in either shoe compared to walking barefoot increased gait speed and stride length. These increases were similar between groups. Although increased walking speeds have demonstrated reduced durations of spinal loading during gait (Callaghan et al., 1999) and are hence proposed to be beneficial to people with CLBP, the associated increased stride length observed in the current study has been previously suggested to increase antero-posterior ground reaction forces (Kirtley, 2006), and therefore the loading of the musculoskeletal structures. Hence, it is unclear whether the increases in velocity and stride length in the current study are likely to be beneficial or disadvantageous to a CLBP population. When barefoot gait at six months was compared to baseline no differences were detected within or between groups for change in spatio-temporal parameters. This indicates that long term use of either footwear type did not influence walking speed, stride length or cadence. Hence, if spatio-temporal parameters of gait are underpinning mechanisms of CLBP it is unlikely that a rocker sole shoe would provide any greater or lesser long term influence on these mechanisms than a flat sole shoe.

Flat sole shoes induced greater increases in range of movement at the hip than rocker sole shoes. These findings agree with previous research demonstrating reduced hip range of movement whilst walking in rocker sole compared to flat sole shoes (Romkes et al., 2006; Taniguchi et al., 2012). However, there is also research detecting no difference in hip joint range between the rocker and flat sole shoes (Demura and Demura, Epub ahead of print; Nigg et al., 2006b).

The reduced hip range observed in people with CLBP has been hypothesised as a mechanism to alleviate pain in the low back region (Lee et al., 2007). If true, due to the reduced hip range observed during gait in the rocker sole shoe, compared to a flat sole shoe, a rocker sole shoe may assist in pain relief. However, findings from the main study *(Chapter 5, p61)* demonstrate similar changes in pain in both groups at all assessment points, hence, it is unlikely that this hypothesis is correct for the angular joint change demonstrated in the current study. This will be discussed further in Chapter 10. When barefoot gait at six months was compared to baseline no differences were detected within or between groups for hip range of movement. This indicates that long term use of either shoe type did not influence barefoot hip range of movement during gait. If hip range of movement does contribute to the symptoms of CLBP, it is unlikely that a rocker sole shoe would provide any greater or lesser long term influence on CLBP symptoms than a flat sole shoe.

There were no changes in peak knee flexion angle during the first half of stance for barefoot and shod gait for either shoe group, nor were any differences between the shoe groups demonstrated. These findings concur with previous research investigating the effect of rocker sole and flat sole shoes on peak knee flexion during the first half of stance (Nigg et al., 2006b; Romkes et al., 2006). In contrast, Taniguchi et al. (Taniguchi et al., 2012) demonstrated a greater peak knee flexion during early stance when walking in rocker sole shoes compared to flat sole shoes. The population in their study was younger than in the current study, otherwise methodologies differences do not appear to account for the difference in findings. It may be that differences in design of the flat sole shoe between studies may account for the difference in findings, as peak knee flexion in rocker sole shoes was similar between studies. If peak knee flexion angle does influence CLBP, due to the lack of change in peak knee flexion angle during barefoot and shod gait within and between groups in the current study, it is unlikely that a rocker sole shoe would provide any greater or lesser long term influence on CLBP than a flat sole shoe.

The current study demonstrated no difference in the incidence of transient force peaks between flat and rocker sole shoes during shod gait (14.3% and 5.8% respectively). Vernon et al. (2004), in an unpublished study, reported that transient force peaks occurred more frequently when walking in normal shoes than in rocker sole shoes (59% and 27% of trials respectively). These contrasting study findings may be due to the differences in shock attenuation properties of the ‘normal shoes’ worn by participants in the different studies (in Vernon et al.’s (2004) study participants wore their own exercise shoes) or due to the gait speed as transient force peaks are more likely to occur at faster walking speeds, however, information on this parameter is omitted in Vernon et al’s study. If transient force peaks are detrimental to CLBP, due to the similar effect of both shoe types in reducing the occurrence of these peaks, it is unlikely that a rocker sole shoe would provide any greater or lesser influence on CLBP symptoms than the flat sole shoe investigated in the current study.

No differences were detected within or between groups for peak hip flexor or extensor moments at six months compared to baseline. This suggests that neither shoe had a long term influence on joint loading around the hip. If increased hip extensor moments contribute to the symptoms of CLBP, it is unlikely that a rocker sole shoe would provide any greater or lesser long term influence on this factor than a flat sole shoe.

8.5.1 Clinical implications

Long term use of rocker sole shoes or flat sole shoes in addition to attendance to a four week exercise group does not appear to influence barefoot walking speed, stride length, sagittal hip moments or sagittal hip range of movements in people with CLBP. Furthermore both shoe types have a similar influence on reducing transient force peaks at heel strike compared to barefoot walking. From these findings, clinicians should feel confident to advise patients with CLBP that long term use of either rocker sole or flat sole shoes will not influence barefoot postural stability, or spatio-temporal, kinetic, or kinematic parameters of gait.

8.5.2 Further research

It is possible that the parameters chosen to investigate changes in gait pattern due to the intervention are insensitive to genuine changes in movement. More direct measures of muscle function, for example EMG, may provide greater insight into underlying biomechanical mechanisms that may be promoting the observed improvement in pain and disability.

One of the limitations is that both shoes had a force transient reducing effect. It is possible as indicated by Vernon et al. (2004) that normal 'everyday' shoes with harder heels may promote transients and delay improvement of pain and disability. This could be tested in a future study.

8.6 Conclusions

This is the first RCT with long term (six month) follow-up comparing the influence of rocker sole and flat sole shoes on spatio-temporal, kinetic and kinematic parameters of gait in a chronic pain population.

Between groups differences at baseline were detected only for change in hip range of movement during barefoot and shod gait. The findings from the main study, demonstrating no difference in clinical outcome between groups, suggest that this biomechanical difference is unlikely to influence outcome in those with CLBP.

There were no long term effects on spatio-temporal, kinetic or kinematic parameters of gait for either group when walking barefoot at six months when compared to baseline. This suggests that no long term training effect, capable of influencing the spatio-temporal, kinetic and kinematic parameters of gait, occurred from wearing either a rocker sole or a flat sole shoe.

9 A comparison of gait and postural control in standing in people with and people without chronic low back pain.

9.1 Chapter summary

This study investigated differences in gait and postural control in people with and without chronic low back pain (CLBP). Barefoot standing postural stability and gait data from the CLBP participants in Chapters 7 *(p148)* and 8 *(p170)*, respectively, were compared with that from age- and gender-matched asymptomatic participants. People with CLBP presented with similar postural stability for stable and more challenging standing conditions to asymptomatic individuals. CLBP participants increase hip and ankle strategies in similar proportions to the asymptomatic individuals during more challenging standing circumstances. During gait, both groups presented with similar spatio-temporal parameters. In contrast to previous research, these findings suggest that for those with CLBP of mild to moderate intensity, postural control during standing, and the kinetics, kinematics, and spatio-temporal parameters of gait do not differ significantly from people without LBP.

9.2 Introduction

Differences in postural control (Brumagne et al., 2008; Della Volpe et al., 2006; Mientjes and Frank, 1999; Mok et al., 2004) and gait (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007; Vogt et al., 2003; Vogt et al., 2001) have been identified between people with and without CLBP. During more challenging standing conditions people with CLBP have demonstrated increased centre of pressure displacements and velocities (Brumagne et al., 2008; Della Volpe et al., 2006; Mientjes and Frank, 1999; Mok et al., 2004), indicative of poorer postural stability (Ruhe et al., 2010; Ruhe et al., 2011a). During gait, people with CLBP have demonstrated reduced self-selected walking speed (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007), stride time (Vogt et al., 2003; Vogt et al., 2001), stride length (Al-Obaidi et al., 2003; Keefe and Hill, 1985), and range of hip movement (Vogt et al., 2003). As a result of these changes, hip moments are likely to be reduced in people with CLBP compared to asymptomatic individuals due to the differences in spatio-temporal parameters of gait (reduced stride length, walking speed and hip range of movement) reported in detail in *8.2 (p170)* (Apkarian et al., 1989). These differences in postural control and gait have been proposed as contributing factors to the presence and recurrent nature of CLBP (Brumagne et al., 2008; Mok et al., 2004; Voloshin and Wosk, 1982).

No previous study replicates the exact methodologies conducted in Chapters 7 *(p148)* and 8 *(p170)*, making direct comparison between these studies and previous studies difficult. Therefore, to determine whether barefoot postural control and gait data from the CLBP participants recruited in Chapters 7 *(p148)* and 8 *(p170)* differs from age- and gender-matched asymptomatic participants, a further study was conducted. The recruitment of an age- and gender-matched asymptomatic sample, undertaking the barefoot baseline standing and gait protocol described in Chapters 7 *(p148)* and 8 *(p170)* enabled direct comparison to be made between asymptomatic and CLBP participants, hence increasing the certainty of study conclusions. This study investigated the following hypotheses:

Null hypothesis (H_0):

Standing hypotheses

H_0 1: The CLBP group and asymptomatic group will demonstrate similar postural stability in the antero-posterior direction during stable and challenging barefoot standing conditions.

H_0 2: Under more challenging standing conditions the asymptomatic and CLBP group will control their balance using a similar postural strategy.

Gait hypotheses

H_0 3: Similar self-selected walking speed, stride time and step length will be observed in people with CLBP and asymptomatic individuals.

H_0 4: During gait, people with CLBP will present with a similar hip range of movement to asymptomatic individuals.

H_0 5: During gait, people with CLBP will present with similar peak hip moments during the stance phase of gait to asymptomatic individuals.

Alternative hypothesis (H_0):

Standing hypotheses

H_1 1: Both groups will demonstrate similar postural stability in the antero-posterior direction during stable standing conditions. However, the CLBP group will demonstrate poorer postural stability in the antero-posterior direction when compared to the asymptomatic group during more challenging barefoot standing conditions.

H_1 2: Under more challenging standing conditions the asymptomatic group will control their balance using a strategy which includes a greater element of control at the hip than the CLBP group.

Gait hypotheses

H_1 3: Reduced self-selected walking speed, stride time and step length will be observed in people with CLBP compared to asymptomatic individuals.

H_1 4: During gait, people with CLBP will present with a reduced hip range of movement compared to asymptomatic individuals.

H_1 5: During gait, people with CLBP will present with reduced peak hip moments during the stance phase of gait compared to asymptomatic individuals.

9.3 Methods

9.3.1 Design

This trial compared barefoot standing balance and gait data from CLBP participants with that from predominantly age- and gender-matched asymptomatic participants.

9.3.2 Ethical approval

Ethical approval for the recruitment of asymptomatic participants was gained through the King's College London 'Biomedical & Health Sciences, Dentistry, Medicine and Natural & Mathematical Sciences Research Ethics Subcommittee' (research reference: BDM/10/11-71) *(11.33, p317).*

9.3.3 Participant recruitment

Participants in the CLBP group were recruited as described in *6.7 (p118)*. Potential asymptomatic participants - work colleagues and friends of the C.I. (Siân MacRae) or co-researcher (Dr Adam Shortland) - were contacted via email, which included the Participant Information Sheet *(11.34, p318).* Asymptomatic participants were classed as 'asymptomatic' if they reported no history of LBP in the last year. Asymptomatic participants were required to meet all criteria presented in *Table 6.1 (p119),* with the exception of a three month or greater history of LBP, and match in age and gender with a CLBP participant (10/H0724/7). An age range of two years above or below the age of the 'matched' CLBP participant was classed as acceptable.

9.3.4 Assessment

Asymptomatic participants attended one assessment in the gait laboratory at Guy's Hospital. Participants were asked to complete the study consent form *(11.35, p321),* Roland Morris Disability Questionnaire and to report a numerical rating score for low back pain (to confirm that asymptomatic participants had no current low back problems) *(7.3.4, p150).* Participants changed into shorts and vest top, and removed their shoes and socks. Anthropometric measurements and the placement of retro-reflective markers were conducted *(7.3.4, p150)* and a short data capture *(6.10.3.2. p136)* recorded with participants barefoot.

Asymptomatic participants were assessed standing *(7.3.4.1, p151)* and walking barefoot *(8.3.4.1, p176).* The biomechanical assessment lasted approximately 30 minutes. Following completion of the walking trials the co-researcher removed all markers from the participant. Participants were informed that the double sided sticky tape used to attach the markers to the skin may leave a red mark on the skin for approximately one hour following marker removal. They were advised that this is normal and should not be of concern. Participants then changed back into their normal clothing and their involvement in the study ended.

9.3.5 Outcome measures

Outcome measures assessed during standing and gait are described in *7.3.5 (p152) and 8.3.5 (p177)*, respectively.

9.3.6 Sample size

The study compared data obtained from CLBP participants (Chapters 6 and 7) with a matched sample of asymptomatic participants. Hence, recruitment of an equal sample size of twenty participants was intended. Sample size calculations were not performed.

9.3.7 Data analysis

Distributions were checked to see if normal distributions had been met, if this was not the case, non-parametric test were performed. Independent t-tests for parametric data, or Mann-Whitney U-tests for non-parametric data, were applied to determine differences between groups. A mixed repeated measures ANOVA with 2 within-subject factors each with 2 levels - vision [eyes open and eyes closed] and support surface [firm ground or foam cushion] determined possible significant main effects and interactions of the two groups for centre of pressure variables. A multivariate analysis of variance (MANOVA) assessed for significant effects of the dependent variables $CoP_{RMSE\ AP}$ and $CoP_{VEL\ AP.}$

The alpha level for determining statistical significance was set at 0.05. The reasoning underpinning choice of statistical tests has been described in *6.11.3.2 (p146).*

Data were analysed using IBM SPSS 20.0.0 (IBM, New York). Results are presented as means (standard deviations (SD)) unless otherwise stated.

9.4 Results

9.4.1 Recruitment

During the recruitment period (June 2011-November 2011) sixteen asymptomatic participants were recruited. The recruitment of matched asymptomatic participants, over the age of 50 years, who had not experienced any LBP over the past twelve months proved difficult. This prevented recruitment of the planned sample size of 20 participants. Although no significant differences were detected between ages of the two groups, the CLBP group was on average 3.7 years older than the asymptomatic group.

9.4.2 Baseline characteristics of participants

Demographic characteristics of CLBP and asymptomatic individuals are presented in Table 9.1. No differences were observed between groups.

Table 9.1 Demographic data for chronic low back pain and asymptomatic participants

	Asymptomatic participants (n=16)	Low back pain participants (n=20)	P-value
Gender : Male	8 (50.0%)*	9 (45.0%)*	0.77†
: Female	8 (50.0 %)*	11 (55.0%)*	
Age (years)	37.3 (11.1)	41.0 (12.5)	0.36
Weight (kg)	76.3 (13.6)	74.5 (16.3)	0.74
Height (cm)	173.4 (9.3)	173.6 (8.6)	0.95

Summary measures represent means (SD) or *numbers (percentages). †Chi squared test, otherwise independent t-test.

9.4.3 Participant retention and attrition

There was 100% retention. All sixteen asymptomatic and twenty symptomatic participants completed the data collection process.

9.4.4 Centre of pressure parameters during barefoot standing in people with and without chronic low back pain

No differences were observed between groups for change in root mean squared error and velocity of the centre of pressure in the antero-posterior direction (CoP $_{RMSE\ AP}$ or CoP $_{VEL\ AP}$ respectively) across the four standing condition (mixed repeated measures ANOVA with 2 within-subject factors each with 2 levels - vision [eyes open and eyes closed] and support surface [firm ground or foam cushion]: vision and group interaction: $F(1,33) = 0.93$, $p = 0.34$, $\eta^2 = 0.03$ and $F(1,33)<0.01$, $p = 1.00$, $\eta^2<0.01$ respectively; support surface and group interaction: $F(1,33) = 1.01$, $p = 0.32$, $\eta^2 = 0.03$ and $F(1,33) = 0.12$, $p = 0.73$, $\eta^2<0.01$ respectively; vision, support surface and group interaction: $F(1,33) = 2.70$, $p = 0.11$, $\eta^2 = 0.08$ and $F(1,33) = 0.02$, $p = 0.90$, $\eta^2 <0.01$ respectively) (Table 9.2). However, although not significantly different, there was a tendency for people with CLBP to be less stable than asymptomatic individuals across all standing conditions (Figure 9.1 and 9.2).

A MANOVA analysing the dependent variables CoP $_{RMSE\ AP}$ and CoP $_{VEL\ AP}$ demonstrated no difference between groups for each standing condition (eyes open no cushion: $F(2,33) = 1.16$, $p = 0.33$, $\eta^2 = 0.07$; eyes closed, no cushion: $F(2,33) = 0.91$, $p = 0.41$, $\eta^2 = 0.05$; eyes open, cushion: $F(2,33) = 0.42$, $p = 0.64$, $\eta^2 = 0.03$; eyes closed, cushion: $F(2,32) = 2.85$, $p = 0.07$, $\eta^2 = 0.15$).

Table 9.2 Antero-posterior centre of pressure parameters for chronic low back pain and asymptomatic participants during different standing conditions

		CoP $_{RMSE\ AP}$ [mm]	CoP $_{VEL\ AP}$ [mm/s]
Eyes open no cushion	Asymptomatic	3.87 (3.42-4.33)	6.28 (5.38-7.18)
	Symptomatic	4.64 (3.73-5.55)	7.02 (6.01-8.03)
Eyes closed no cushion	Asymptomatic	4.04 (3.28-4.79)	7.48 (6.52-8.45)
	Symptomatic	4.76 (3.90-5.61)	8.23 (7.10-9.35)
Eyes open cushion	Asymptomatic	8.71 (7.83-9.61)	15.09 (13.09-17.01)
	Symptomatic	9.37 (8.13-10.61)	15.42 (13.86-16.98)
Eyes closed cushion	Asymptomatic	9.90 (9.07-10.73)	26.13 (22.11-30.15)
	Symptomatic	11.66 (10.42-12.89)	26.35 (21.65-31.06)

Summary measures represent means (95% Confidence Intervals). (RMSE: root-mean squared error; AP: antero-posterior; VEL: velocity)

Figure 9.1 Root mean squared error of centre of pressure displacement in the antero-posterior direction for chronic low back pain and asymptomatic participants during different standing conditions

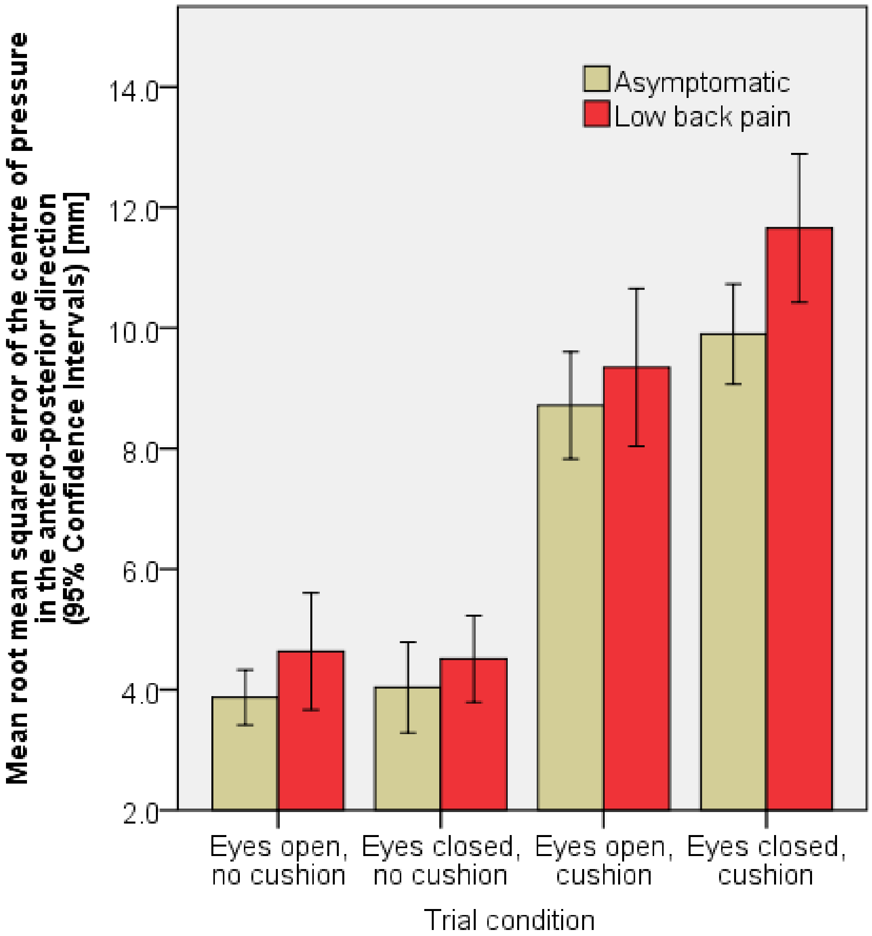
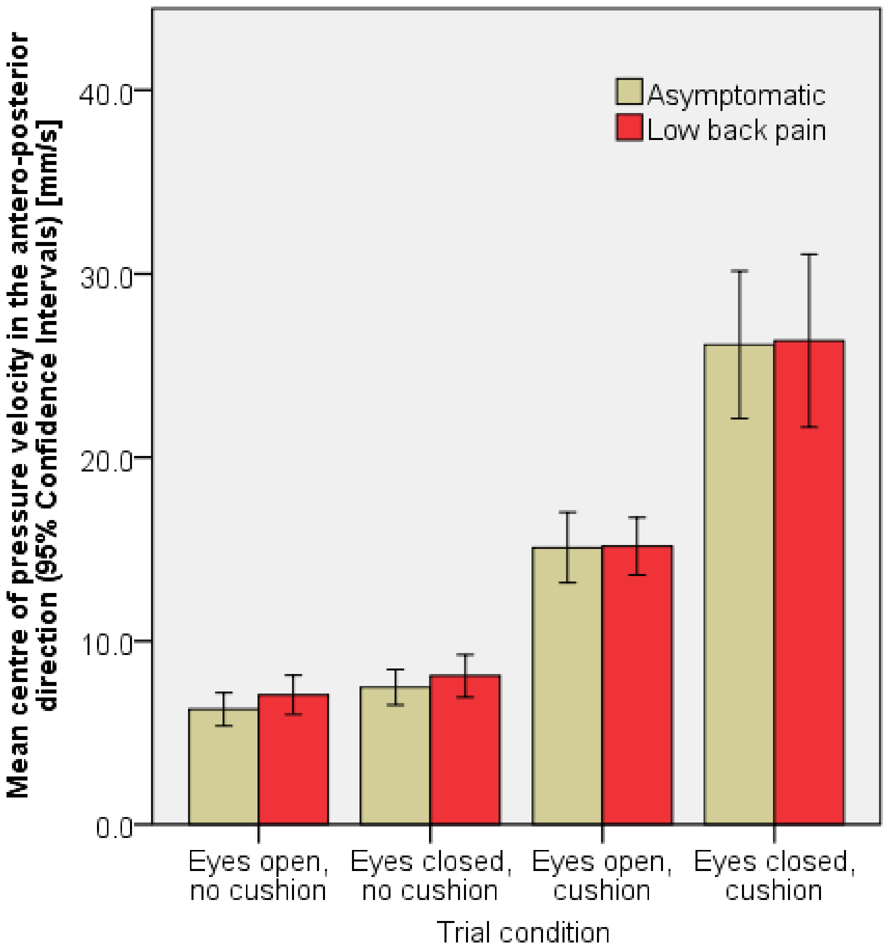


Figure 9.2 Antero-posterior centre of pressure velocity for chronic low back pain and asymptomatic participants during different standing conditions



9.4.5 Postural strategy during standing in people with and without chronic low back pain

No differences were observed between groups for left or right hip:ankle postural control index across the four standing condition when assessing interactions between: group and vision; group and ground surface; and vision, support surface and group (mixed design factorial repeated measures ANOVA with 2 within-subject factors each with 2 levels: vision [eyes open and eyes closed], and support surface [firm ground or foam cushion] : vision and group interaction: $F(1,33) = 1.19$, $p = 0.28$, $\eta^2 = 0.04$ and $F(1,33) = 0.86$, $p = 0.36$, $\eta^2 = 0.03$ respectively; support surface and group interaction: $F(1,33) = 1.49$, $p=0.23$, $\eta^2 = 0.04$ and $F(1,33) = 3.22$, $p = 0.08$, $\eta^2 = 0.09$ respectively; vision, support surface and group: $F(1,33) = 0.38$, $p = 0.54$, $\eta^2 = 0.01$, and $F(1,33) = 4.26$, $p = 0.05$, $\eta^2 = 0.11$) (Table 9.3).

Table 9.3 Hip:ankle postural control index for chronic low back pain and asymptomatic participants during different standing conditions

		Left hip:ankle postural control index	Right hip:ankle postural control index
Eyes open no cushion	Asymptomatic	0.34 (0.11)	0.35 (0.14)
	Symptomatic	0.31 (0.10)	0.36 (0.12)
Eyes closed no cushion	Asymptomatic	0.36 (0.14)	0.31 (0.07)
	Symptomatic	0.32 (0.08)	0.38 (0.13)
Eyes open cushion	Asymptomatic	0.25 (0.07)	0.27 (0.08)
	Symptomatic	0.27 (0.09)	0.26 (0.08)
Eyes closed cushion	Asymptomatic	0.29 (0.07)	0.32 (0.08)
	Symptomatic	0.27 (0.09)	0.29 (0.09)

Summary measures represent means (SD).

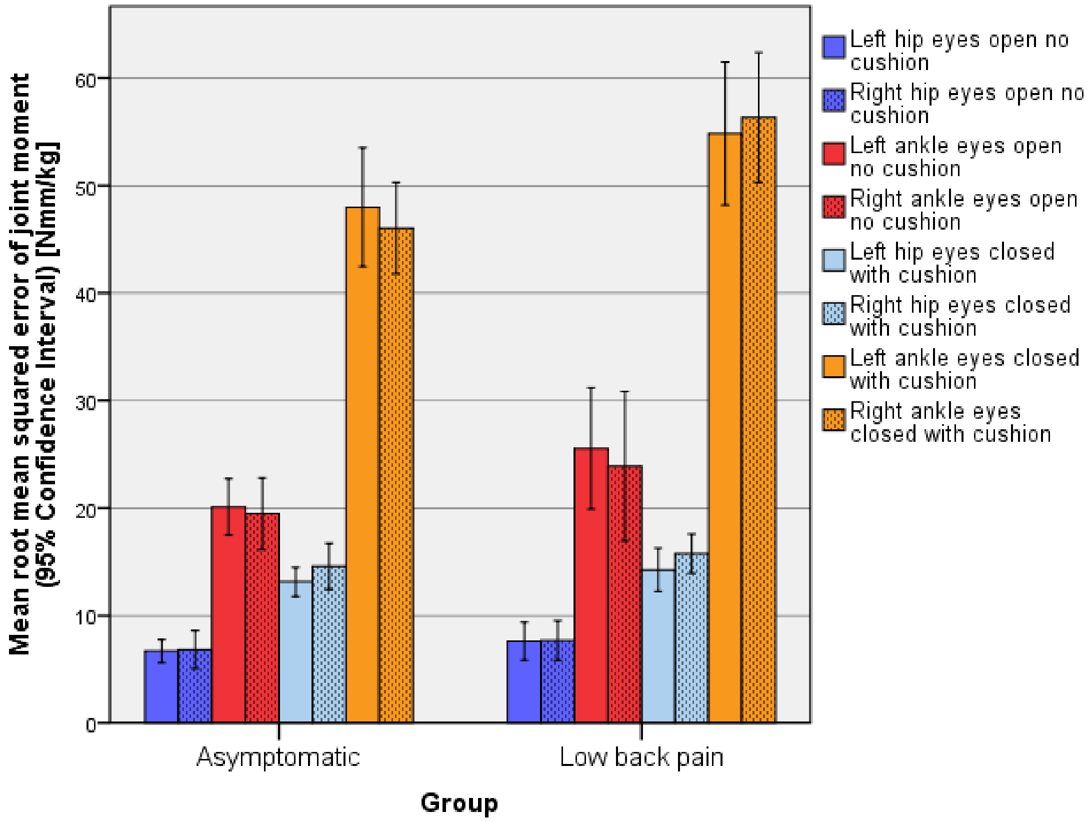
No differences were observed between groups for left or right hip or left or right ankle strategy across the four standing conditions when assessing interactions between: group and vision; group and ground surface; and vision, support surface and group (mixed design factorial repeated measures ANOVA with 2 within-subject factors each with 2 levels: vision [eyes open and eyes closed], and support surface [firm ground or foam cushion]: vision and group interaction:

- Left hip
    - group and vision: $F(1,33) = 0.02$, $p = 0.88$, $\eta^2 <0.01$
    - group and ground surface: $F(1,33) = 0.11$, $p = 0.74$, $\eta^2 <0.01$
    - vision, support surface and group: $F(1,33) = 0.25$, $p = 0.63$, $\eta^2 < 0.01$
- Right hip
    - group and vision: $F(1,33) = 1.14$, $p = 0.29$, $\eta^2 = 0.03$
    - group and ground surface: $F(1,33) = 0.23$, $p = 0.63$, $\eta^2 <0.01$
    - vision, support surface and group: $F(1,33) = 0.28$, $p = 0.60$, $\eta^2 < 0.01$

- Left ankle
  - group and vision: F(1,33) = 0.88, p = 0.36, $\eta^2 = 0.03$
  - group and ground surface: F(1,33) = 0.02, p = 0.89, $\eta^2 < 0.01$
  - vision, support surface and group: F(1,33) = 3.96, p = 0.06, $\eta^2 = 0.11$
- Right ankle
  - group and vision: F(1,33) = 0.41, p = 0.53, $\eta^2 = 0.01$
  - group and ground surface: F(1,33) = 1.78, p = 0.19, $\eta^2 = 0.05$
  - vision, support surface and group: F(1,33) =1.92, p = 0.18, $\eta^2 < 0.06$

Figure 9.3 demonstrates that the CLBP participants increase hip and ankle strategies in similar proportions to the asymptomatic individuals during more challenging standing conditions.

Figure 9.3 Hip and ankle strategy during quiet standing and more challenged standing conditions for chronic low back pain and asymptomatic participants



9.4.5.1 Spatio-temporal parameters of barefoot gait in chronic low back pain and asymptomatic individuals

No differences were observed between groups for any of the spatio-temporal gait parameters assessed (Table 9.4).

Table 9.4 Spatio-temporal parameters of gait in chronic low back pain and asymptomatic individuals

	Asymptomatic	Chronic low back pain	P - value
Walking speed [m/s]	1.32 (0.13)	1.25 (0.20)	0.26
Cadence [steps per minute]	115.14 (6.59)	112.43 (11.81)	0.42
Stride length [m]	1.38 (0.12)	1.33 (0.13)	0.33

Summary measures represent means (SD). Analysis by independent t-test.

9.4.5.2 Hip joint range of movement during barefoot gait

No differences were detected between groups for maximum, minimum and total ranges of movement at the hip in the sagittal plane during gait (Table 9.5).

Table 9.5 Sagittal plane hip range of movement during gait in people with chronic low back pain and asymptomatic individuals [degrees]

	Asymptomatic	Chronic low back pain	P - value
Left maximum hip flexion	34.35 (5.55)	33.70 (8.55)	0.78
Right maximum hip flexion	34.46 (4.51)	33.82 (9.17)	0.79
Left maximum hip extension	-9.71 (7.39)	-10.44 (9.02)	0.80
Right maximum hip extension	-9.40 (6.67)	-9.12 (8.74)	0.92
Left hip range of movement	44.07 (3.94)	44.14 (4.79)	0.97
Right hip range of movement	43.85 (3.71)	42.94 (4.44)	0.51

Summary measures represent means (SD). Analysis by independent t-test.

9.4.5.3 Joint moments during gait

No differences were observed between groups for hip joint moments during gait (Table 9.6).

Table 9.6 Hip and ankle joint moments during gait in people with chronic low back pain and asymptomatic individuals

Joint moment [Nmm/kg]	Asymptomatic	Chronic low back pain	P - value
Left hip extensor	1029.30 (329.38)	955.80 (429.78)	0.58
Right hip extensor§	960.99 (235.24)	1029.57 (460.62)	0.94
Left hip flexor	-990.76 (184.25)	-1098.07 (231.85)	0.14
Right hip flexor	-1041.87 (174.80)	-977.77 (194.64)	0.31

Summary measures represent means (SD).§ represents Mann-Whitney test for non-parametric data, otherwise Independent t-test conducted.

9.5 Discussion

In contrast to much other research, the current findings suggest that postural control during standing, and the kinetics, kinematics, and spatio-temporal parameters of gait do not differ between people with CLBP of a mild to moderate intensity and asymptomatic individuals. There were no differences between people with and without CLBP in hip and ankle strategy preferences or postural stability during all standing conditions. During barefoot gait, both groups presented with similar hip joint moments, hip joint ranges of movement, and spatio-temporal parameters of gait.

9.5.1 Comparison of demographic data for the chronic low back pain and asymptomatic population.

Demographic data of participants in both groups were well matched at baseline. Although not significant, the CLBP group was on average 3.7 years older than the asymptomatic group. The difficulties in recruiting matched asymptomatic participants over the age of 50 years, who had not experienced any LBP over the past twelve months lead to this difference, hence although this study aimed to provide a matched asymptomatic population, matching was only possible for sixteen of the CLBP participants. Being over 50 years of age is a contributing factor to poorer postural stability (Choy et al., 2003). Therefore, the absence of these older participants in the asymptomatic group increases the likelihood of detecting differences in CoP parameters between the groups.

9.5.2 Centre of pressure parameters

There was no difference in postural stability between CLBP and asymptomatic individuals during stable and more challenging standing conditions. These findings differ from previous research (Brumagne et al., 2008; Della Volpe et al., 2006; Mientjes and Frank, 1999; Mok et al., 2004) possibly due to methodological variation. Della Volpe et al. (2006) assessed a small sample (n=12 per group) with an 'instrumented platform system', constructed of a moveable support surface and movable visual surround likely to present participants with a greater postural challenge than that in the current study. Such an increased challenge may contribute to the reduced postural stability in the CLBP group in the Della Volpe et al. study (2006). Brumagne et al. (2008) assessed a similar sample size to the current study (n=45), however, trials were only repeated once – the current study averaged three trials per standing condition, likely to increase the reliability of data (Ruhe et al., 2011a). Although Brumagne et al. (2008) reported reduced postural stability in the CLBP group during the more challenging standing conditions (eyes closed on foam) the between group difference in $CoP_{RMSE\ AP}$ was 1.8mm, and the p value, 0.046 – bordering on non-significance. In the current study the non-significant difference in $CoP_{RMSE\ AP}$ between the symptomatic and asymptomatic groups during the most challenging postural condition was 1.76mm. Although Brumagne et al. (2008) demonstrated statistical significance it is unlikely that such a minimal difference in $CoP_{RMSE\ AP}$ is responsible for the clinical differences in pain and disability observed between the two groups. Mientjes and Frank (1999) assessed a small sample (n=8 per group) and although reporting significant differences between CLBP and asymptomatic groups during challenged standing conditions, these differences were small (less than 2mm) and similar to those of both the current study and Brumagne et al. (2008). Furthermore, Mientjes and Frank (1999) report a mean pain score of 0.5 in the 'asymptomatic' group at baseline raising concerns that the asymptomatic data may not be a true representation of a pain free population.

The CoP parameters assessed in a research study may influence the reliability of results. CoP velocity consistently demonstrates the best overall reproducibility of all CoP parameters in both the short and long term (nine months) (Ruhe et al., 2010; Takala et al., 1997b), hence, findings from this parameter are likely to provide more reliable conclusions to those gained from $CoP_{RMSE\ AP}$ data or other CoP parameters. The current study demonstrated similar $CoP_{VEL\ AP}$ in people with and without CLBP, whereas previous research has demonstrated reduced (Mok et al., 2004; Salavati et al., 2009b) (n=24 and 22 per group respectively) and increased (Della Volpe et al., 2006; Lafond et al., 2009; Mann et al., 2010) (n=12, 12, and 10 per group respectively) CoP velocities. These mixed results suggest it likely that research demonstrating no difference between groups has been conducted, however, due to publication bias may not have gained acceptance for publication. Interestingly, the studies conducted with the greater sample size, demonstrate poorer postural control in the asymptomatic groups not the CLBP groups. Furthermore, research demonstrating between group differences in $CoP_{VEL\ AP}$ report differences of less than 4mm/s during more challenging standing conditions (Della Volpe et al., 2006; Lafond et al., 2009; Mann et al., 2010; Mok et al., 2004; Salavati et al., 2009b). It is unlikely that such minimal differences are responsible for the clinical differences in pain and disability between people with CLBP and asymptomatic individuals. Furthermore, findings from previous research (Salavati et al., 2009a; Salehi et al., 2010) highlight that the small differences observed between groups in this study may be due to random error associated with the reliability of the measurement technique and not clinical change.

Difference in participant demographics (for example, age (Della Volpe et al., 2006; Salavati et al., 2009b), gender (Mann et al., 2010) or disability (Mok et al., 2004)), and methodological design (for example, trial duration and repetitions, (Lafond et al., 2009; Mok et al., 2004; Takala et al., 1997b)), make it difficult to directly compare study findings. Due to the numerous factors which may contribute to the variation in CoP outcomes reported, comparison of one study data with another is likely to reveal potential differences, however, choice of outcome measures and the number and duration of trials conducted in the current investigation improves the likelihood that data collected is reliable.

9.5.3 Methods for calculating hip and ankle strategies

Findings from the current study do not suggest that people with CLBP select different postural control strategies from asymptomatic individuals. In asymptomatic individuals it has been proposed that under more challenging standing conditions, the hip musculature would be activated to a greater extent to promote stability than during stable standing

(Horak and Nashner, 1986), whereas people with CLBP would continue to favour an ankle strategy, with little change in contribution from the hip strategy (Brumagne et al., 2008). The current study finding is in contrast to conclusions of other studies which, although employed similar methodologies (Brumagne et al., 2008; Mok et al., 2004), determined the magnitude of each postural strategy from very different approaches.

Brumagne et al. (2008) applied a ratio approach to determine 'relative proprioceptive weighting' calculated from dividing the CoP displacement during mechanical vibration to the calf muscle by the summation of CoP displacement obtained during i.) mechanical vibration of the calf muscle and ii.) mechanical vibration of the lumbar multifidus muscle. In contrast, Mok et al. (2004) inferred a hip strategy from horizontal shear forces, and implied the magnitude of the ankle strategy from displacement of the CoP. However, neither of these calculation methods enabled hip or ankle moments to be measured directly. In the current study, the use of two force plates and the retro-reflective marker set enabled the direct measurement of joint moments. The root mean squared error (RMSE) (a measure of deviation from a signal mean), was calculated for the hip flexor/extensor moment and the ankle plantarflexor/dorsiflexor moment, and the ratio of these two variables determined the hip: ankle postural control index. There is little in the literature regarding the validity of methods assessing postural strategy. However, the ability to directly assess joint moments in the current study as opposed to inferring strategy activity from other measures (such as CoP parameters or horizontal shear forces) increases the likelihood that the method for calculating strategies in the current study is valid. Furthermore, this increases confidence that the current results are a more valid representation of postural strategy in CLBP than that reported in previous research (Brumagne et al., 2008; Mok et al., 2004).

The current study demonstrated a similar hip strategy between people with CLBP and asymptomatic individuals during stable and more challenging standing conditions (*Figure 9.3, p200),* challenging the suggestion that people with CLBP have a reduced ability to initiate a hip strategy during more challenging standing tasks (Brumagne et al., 2008; Mok et al., 2004). The proposed reduced hip strategy in people with CLBP has been suggested to result from co-contraction of superficial muscles at the hip (Mok et al., 2004). The current study suggests that, if a difference existed in muscle co-contraction around the hip between people with and without CLBP, it did not influence the hip strategy.

9.5.4 Gait

It was hypothesised that people with CLBP would present with a reduced walking speed, cadence and stride length compared to asymptomatic individuals. However, no differences were detected in these spatio-temporal parameters between groups. In support of the current study findings, Al-Obaidi et al. (2003) and Simmonds et al. (1997) demonstrated no difference in cadence and self-selected walking speed respectively between people with and without CLBP (with a similar age and gender to those in the current study), whilst walking on normal ground. However, previous research investigating participants with similar self-reported pain and disability (mild to moderate) to the current study demonstrated reduced walking speed (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007), stride time (Vogt et al., 2003; Vogt et al., 2001), and stride length (Al-Obaidi et al., 2003; Keefe and Hill, 1985) in people with LBP. The current study averaged data from three trials for each participant, aiming to improve reliability (Ruhe et al., 2010), whereas other studies analysed data from only one walking trial (Al-Obaidi et al., 2003; Lee et al., 2007; Vogt et al., 2003), possibly reducing data reliability. In addition, where other studies investigated predominantly (Keefe and Hill, 1985) or all male (Lee et al., 2007; Vogt et al., 2003) participants, the current study assessed male and female subjects, enabling findings to be more representative of a general population. Furthermore, the current study assessed participants walking on normal ground, as opposed to on a treadmill (Lamoth et al., 2002; Vogt et al., 2003; Vogt et al., 2001), hence the current study findings are likely to be more representative of a natural walking pattern. These factors increase confidence that the current results are a more reliable and more valid representation of gait in CLBP than that reported in previous research (Al-Obaidi et al., 2003; Keefe and Hill, 1985; Lamoth et al., 2002; Lee et al., 2007; Vogt et al., 2003; Vogt et al., 2001)

In contrast to the current study, previous research has reported reduced hip range of movement in people with LBP during gait compared to asymptomatic individuals (Vogt et al., 2003). This may be due to co-contraction of muscles crossing the hip and pelvic region (Hodges and Moseley, 2003) limiting hip movement, or from participants reducing step length, and hence hip range, in an attempt to reduce potentially detrimental GRFs at heel strike (Light et al., 1980; Voloshin and Wosk, 1982). The reduced hip range demonstrated by Vogt et al. (2003), occurred during treadmill gait, whereas the current study assessed people walking on normal ground hence likely to be more representative of a natural gait pattern. Furthermore, Vogt et al (2003) assessed hip range by attaching an electrical goniometer to the greater trochanter. This method of assessment provides less reliable data than the retro-reflective marker system utilised in the current study (Pomeroy et al., 2006; Rowe et al., 2001). These methodological differences increase confidence that the current results are a more valid representation of gait in CLBP than that reported in previous research (Vogt et al., 2003). In the current study, due to the lack of difference in stride length between CLBP and asymptomatic individuals, the similar range of hip movement between the two groups was an expected finding.

9.5.5 Strengths and Limitations

Although the sample size of the current study is small, possibly contributing to the occurrence of type II errors, a larger number of participants were assessed compared to most previous studies investigating postural control and gait in CLBP and asymptomatic individuals (Brumagne et al., 2004; Della Volpe et al., 2006; Lafond et al., 2009; Mann et al., 2010; Mientjes and Frank, 1999). This increases the likelihood that the current study findings are more representative of the larger CLBP population.

Difficulties recruiting asymptomatic participants over the age of 50 who had no history of LBP in the past year may have increased the likelihood that differences in CoP parameters, between the groups, would be detected. This is due to the negative association between age and postural stability. Improved matching in the asymptomatic group, to include the four asymptomatic individuals over the age of 50, omitted from this study, is likely to increase not decrease CoP parameters in the asymptomatic group. This increases confidence in the current study's findings that people with CLBP do not present with poorer postural stability than asymptomatic individuals.

The current study recruited CLBP participants from clinical populations, who had sought medical opinion regarding their symptoms and hence represented a typical population treated within physiotherapy departments. Previous research has recruited participants from alternative sources such as university populations (Mok et al., 2004) which may not be representative of the sub-group of CLBP individuals who seek medical help and advice; hence caution should be taken if relating findings from such studies to a person with CLBP who is attending for treatment.

9.5.6 Further research

The velocity of the CoP is reported as the most reliable CoP parameter, however it is unclear if this measure is the most appropriate to detect difference in postural stability. Hence, a difference in postural control between the symptomatic and asymptomatic groups may have been present, but not detected. Alternative balance measures could be investigated, such as time to fail in a single leg stand, or the forward reach test to determine whether more functional or challenging outcomes possess the necessary discriminatory value to detect differences in balance in people with and without CLBP (and assist in confirming whether such differences exist).

The current research suggests that 'dysfunctions' in standing postural control and kinematic, kinetic and spatio-temporal parameters of gait are unlikely to present in a CLBP population with mild to moderate disability and pain. Future research investigating treatments aimed at 'correcting' postural stability, hip and ankle strategies, or gait dysfunctions in people with CLBP is likely to be inappropriate.

9.5.7 Clinical implications

The current study assessed a larger sample than the majority of previous research investigating similar outcome measures in people with and without LBP. Therefore, it is likely that this study will provide clinicians with more robust and reliable conclusions. Based on the findings of this study, clinicians should feel confident that standing postural stability, kinetic, kinematic and spatio-temporal parameters of gait in people with and without mild to moderate CLBP do not differ, and that treatments directed at influencing postural stability (for example, standing on a wobble board) or specific parameters of gait may be an unnecessary addition to a treatment programme.

9.6 Conclusions

This study suggests that people with CLBP and asymptomatic individuals present with similar standing postural control, and kinetic, kinematic and spatio-temporal parameters of gait.

- There were no between group differences in change in postural stability over the four standing conditions.
- There were no between group differences in change in hip strategy over the four standing conditions.
- There were no between group differences in change in ankle strategy over the four standing conditions
- There were no between group differences in change in hip: ankle postural control index over the four standing conditions.
- Both groups presented with similar hip range of movement during gait.
- During gait, people with CLBP demonstrated similar walking speeds, stride lengths and cadences to the asymptomatic individuals.

10 Discussion

10.1 Aim of chapter

The importance of this thesis is briefly restated, followed by a summary of findings from the studies conducted within this thesis. Conclusions from the biomechanical studies are related to those in the main study. Explanations for differences in findings between current and previous research are proposed. The clinical relevance of the research is discussed and topics for further research are presented.

10.2 The importance of this thesis

Mechanisms underpinning chronic low back pain (CLBP) remain unclear. Recommended treatment approaches, such as exercise therapy, generally demonstrate only mild improvement in symptoms (Keller et al., 2007). Although many mechanisms have been proposed to underpin CLBP, a lack of knowledge regarding which mechanism is the most relevant to target through treatment may account for the minimal long term improvement in people with CLBP.

Many of the proposed mechanisms underpinning CLBP relate to trunk and lower limb biomechanics, hence treating the spine in isolation appears inappropriate (McGregor and Hukins, 2009). Incorporating more distal regions of the body into rehabilitation programmes for CLBP may offer improved outcomes. This hypothesis is supported by McGregor and Hukins (2009) who propose that lower limb abnormalities, especially at the hip, in people with CLBP, may result from or be a contributing factor to LBP symptoms.

Shoe manufactures have claimed that their shoes can influence lower limb and spinal biomechanics (Masai Barefoot Technology GB Ltd, 2011). The average UK person walks approximately 188 miles (303km) per year (Department of Transport, 2011), hence, if rocker sole shoes positively influence mechanisms underpinning CLBP, wearing such shoes during a daily functional activity such as walking may improve clinical outcome for people with CLBP, particularly if the LBP is aggravated by walking. Prior to the current thesis, there was a lack of research investigating the effectiveness of rocker sole shoes in CLBP to substantiate such claims.

10.3 Summary of findings

The main clinical study *(Chapter 5, p61)* demonstrated that wearing rocker sole shoes or flat sole shoes results in similar outcomes in the short and long term management of mild to moderate CLBP. However, if a person's pain is aggravated by standing or walking, wearing rocker sole shoes may be detrimental to clinical improvement.

The biomechanical studies *(Chapters 7, p148 and 8, p170)* demonstrated no long term effects on barefoot postural control, kinetics, kinematics or spatio-temporal parameters of gait from wearing either shoe type. Although some immediate biomechanical differences were observed between groups when shod compared to barefoot, the lack of between group differences in outcomes in the main clinical study suggests it unlikely that the minimal differences in the parameters assessed influence clinical outcome in people with CLBP.

No participants reported any adverse effects; however, two participants withdrew from the rocker sole group due to the occurrence of a blister and the fear of blister occurrence. These reasons for withdrawal, in addition to the lower participant satisfaction scores and greater number of participants lost to follow up in the rocker sole group suggest the rocker sole shoes were less acceptable.

Comparison of biomechanical parameters of participants with CLBP and age- and gender-matched asymptomatic individuals *(Chapter 9, p189)* demonstrated no significant difference in spatio-temporal, kinetic or kinematic parameters. This suggests that although the mechanism(s) underpinning back pain remain equivocal, for people with mild to moderate CLBP, pure biomechanical mechanisms are unlikely.

10.4 Similarity in clinical outcome between groups

The mild to moderate similar improvement in clinical outcome between interventions in the main clinical study, concurs with findings from many other studies investigating physiotherapy treatments and other treatments for CLBP (Cairns et al., 2006; Critchley et al., 2007; Frost et al., 2004; Hay et al., 2005; Hayden et al., 2005b). Explanation for this consistent finding include: i) a greater effect was gained from one intervention than the other but the effect was not detected by the outcome measures assessed; ii) the interventions had no influence on CLBP – within group reductions in disability and pain resulted from the natural history of the condition, and not due to either interventions influence; iii) sub-groups within the sample may have improved, however, these findings were diluted by the heterogeneous nature of CLBP or; iv) improvements in disability and pain resulted from effects common to both intervention groups. These four explanations are discussed in greater detail below.

A range of recommended outcome measures, sensitive to clinical change were assessed in both the clinical study (Bombardier, 2000; Deyo et al., 1998) and the biomechanical studies (Ruhe et al., 2010; Ruhe et al., 2011a). The consistent finding of no difference between shoe groups for any of the measures assessed at any follow-up point in either the main clinical or biomechanical studies adds strong support to study conclusions that clinical difference between the groups did not occur.

It is well documented that people with conditions such as back pain seek medical interventions at the peak of their symptoms (Dunn et al., 2006), and that natural improvement is likely to follow. It is possible that the reductions in disability and pain, reported in the main clinical study, may have resulted from the natural history of the condition and not from a participant's involvement in the study. This has been discussed in *Chapter 5 (p61).* However, this theory, suggesting that the intervention (shoe type) had no influence on participants' improvement, does not account for the poorer outcome in the rocker sole shoe sub-group reporting pain at baseline aggravated by standing or walking activities.

The sub-group analysis of participants reporting pain on standing or walking demonstrated poorer outcomes at one year in the rocker sole shoe group than the flat sole shoe group. This supports the hypothesis that sub-groups within the heterogeneous non-specific LBP population exist (Foster et al., 2011). The current research suggests that therapists should be mindful of a patient's self-reported aggravating factors, such as pain during standing activities, when planning treatment approaches as these factors may influence outcome; further research to determine appropriate clinical sub-groups may influence treatment choice and improve outcome for those with CLBP.

The fourth explanation suggests that reductions in disability and pain may have resulted from effects common to all interventions. In the current study participants in both groups attended a back exercise class, received a free pair of shoes, were encouraged to increase daily activity through walking, and received long term follow-up from a physiotherapist. Increasing physical activity is recommended for people with CLBP (NICE, 2009). A Cochrane review of interventions that promote physical activity concluded that a mixture of professional guidance and on-going professional support can encourage adults to be more physically active (Foster et al., 2005). Walking has been suggested as a beneficial treatment approach for those with CLBP (McDonough et al., 2010). Long term follow-up resulted in the participant meeting with the chief investigator on four occasions during the main clinical study and if participating in the biomechanical studies, a further three meetings. During these assessments, a positive influence on treatment outcome may have resulted from the therapist-patient relationship (Hall et al., 2010). In addition, informal advice received during these assessments and participants being able to talk about their back problems may have reduced fear avoidance behaviours and improved coping strategies which have been reported to correlate with improvements in CLBP (Mannion et al., 2001). Furthermore, receiving a free pair of shoes may have resulted in a positive placebo effect influencing outcome. These factors may have contributed to the similar positive outcome in both shoe groups.

The gait laboratory was not local for the majority of participants. This provides a further explanation for the similarity between CLBP and asymptomatic groups. People with greater self-reported pain have demonstrated poorer postural stability (Ruhe et al., 2011b); this sub-group with greater postural control impairments or greater mobility problems may have declined to participate in the biomechanical study as a consequence of the journey to the laboratory, whereas those with mild to moderate symptoms were happier to travel. This is supported by the reduced mean self-reported pain and disability in the biomechanical study participants compared to the main clinical study participants (pain: 5.93 and 6.61 respectively; disability: 6.45 and 8.52 respectively).

10.5 Is treatment for chronic low back pain directed at the mechanisms responsible for the symptoms?

In contrast to much previous research (Byl and Sinnott, 1991; Della Volpe et al., 2006; Keefe and Hill, 1985; Khodadadeh and Eisenstein, 1993; Luoto et al., 1996; Mientjes and Frank, 1999; Mok et al., 2004; Moseley and Hodges, 2005; Takala et al., 1997a; Vogt et al., 2001), this thesis demonstrated similar biomechanical parameters in people with and without CLBP. The similarities between groups question whether proposed biomechanically based unpinning mechanisms of CLBP are correct. Alternatively, biomechanical mechanisms may underpin CLBP, but between group differences were undetected due to insensitivity of the measures used in this thesis. However, for reasons discussed in *Chapter 9 (p189)* the latter is unlikely. The thesis findings therefore question whether treatment directed at influencing biomechanical mechanisms thought to underpin back pain is a valuable use of treatment time. A systematic review demonstrating no relationship between clinical and physical outcomes following exercise interventions (Steiger et al., 2012), supports the suggestion that biomechanical mechanisms are unlikely.

Small differences in biomechanical parameters were demonstrated between the rocker sole and flat sole groups when comparing barefoot with shod assessments with some changes hypothesised as beneficial and others detrimental to CLBP (for example, increased hip range of movement [in flat sole shoes] may be detrimental to CLBP due to a concomitant increase in spine movement, activity of the surrounding muscles, or spinal loading). However, the main clinical study demonstrated similar outcomes between shoe groups suggesting that the minimal biomechanical differences observed between groups from barefoot to shod are unlikely to result in clinical change. Furthermore, the lack of change in barefoot biomechanical parameters at six months follow-up, where participants reported clinical improvement in pain and disability, suggests that improvements in disability and pain were unlikely to have resulted from a biomechanical influence. Findings from previous research support this suggestion (Mannion et al., 2012; Steiger et al., 2012).

Proprioceptive treatment approaches are common practice in knee (Fitzgerald et al., 2000) and ankle rehabilitation (Tropp and Askling, 1988), and have been recommended in the management of CLBP (Johanssen et al., 1995). The current research indicates that wearing an unstable sole, challenging postural stability, has no greater benefit to pain and disability in the short or long term when compared to wearing a flat sole shoe. This suggests that for those with CLBP a specific proprioceptive rehabilitation programme performed whilst standing is no more beneficial than a general exercise programme alone, and may be detrimental for people with pain aggravated whilst standing or walking. The lack of change in barefoot postural parameters at six months compared to baseline in the rocker sole shoe group questions whether postural control can be 'trained' through such a balance orientated management programme in people with mild to moderate CLBP. The similarities in postural control between the CLBP population and the asymptomatic individuals *(Chapter 9, p189)* further questions whether treatments directed at improving postural control is a necessary or appropriate rehabilitation goal in CLBP management. However, if the CLBP group had presented with greater postural instability at baseline (possibly present in individuals with more severe pain (Ruhe et al., 2011b) or higher disability than participants in the current research) then a training effect may have been observed.

Anxiety and depression are predictors of outcome for people with CLBP (Trief et al., 2000). If anxiety and depression levels reduce, a concomitant reduction in disability and pain may be expected. Therefore, it has been recommended that management of CLBP incorporates not only physical rehabilitation but a more bio-psychosocial approach. However, in the main clinical study, although pain and disability improved at one year follow-up compared to baseline, anxiety and depression did not change. This implies that factors other than anxiety and depression contributed to the observed clinical improvement. If higher baseline anxiety and disability scores had been reported, a reduction in these outcomes may have correlated with pain and disability improvements (Mannion et al., 2001).

Minimal improvements are frequently observed in RCTs investigating the effects of conservative treatments for CLBP, with a lack of correlation between change in pain and change in the hypothesised underpinning mechanisms (Steiger et al., 2012). This questions whether current treatments are directed at influencing correct underpinning mechanisms but with little effect, or are designed to influence epiphenomena - secondary symptoms occurring alongside a disease or condition but not directly related to its cause (Stedman, 2005) - hence may be targeting the wrong pathways. Recent research has demonstrated reductions in volume and a change in biochemical composition of certain regions of the brains' gray matter, thought to be associated with the transmission of pain, in individuals with CLBP (Apkarian et al., 2004; Grachev et al., 2000; Grachev et al., 2003; Schmidt-Wilcke et al., 2006). Magnetic resonance imaging scanning has identified gray matter decreases in the dorsolateral prefrontal cortex and brainstem and magnetic resonance spectroscopy has demonstrated reductions in N-acetly aspartate (a brain specific metabolite) in the dorsolateral prefrontal cortex, indicative of neuronal loss or dysfunction (Apkarian et al., 2004; Grachev et al., 2000; Grachev et al., 2003; Schmidt-Wilcke et al., 2006). It is unclear whether these volume and biochemical changes may be the cause of, the result of, or are unrelated to the concomitant chronic pain state. The dorsolateral prefrontal cortex integrates motor and sensory information (Fink et al., 1999). It may be that atrophy or a reduction in volume of this region of the brain has a negative influence on sensory-motor feedback. This altered feedback may contribute to the presence of epiphenomena incorrectly assumed by researchers and clinicians to be the underpinning mechanisms of CLBP. The biomechanical mechanisms considered in this thesis may be examples of such epiphenomena. Such misbeliefs may be misleading and detrimental to researchers investigating appropriate and effective management programmes for people with CLBP.

A further potential underpinning mechanism to explain the presence of CLBP, and direct research towards brain orientated treatments, is the observation of an alternative representation of the lumbar spine in the somatosensory cortex of the brain in people with CLBP compared to asymptomatic individuals (Flor et al., 1997). It has been suggested that an altered cortical representation of somatic input may result in incongruence between motor intention and the resultant movement (Harris, 1999). If there is incongruence between motor output and sensory feedback, it has been hypothesised that pain is produced to warn the individual of the abnormal sensory-motor processing (McCabe et al., 2005). In the sub-group reporting pain on standing and walking the use of a rocker shoe, introducing additional postural instability, may have further increased sensory-motor incongruence, and hence increased the perception of pain. Conditions that generate ineffective sensory-motor processing are associated with increased activation in the right dorsolateral prefrontal cortex (Fink et al., 1999). The over-activation of this brain region may lead over time to excitotoxicity, a possible cause for the dorsolateral prefrontal cortex atrophy (Apkarian et al., 2004). For the sub-group analysed, the addition of an unstable standing surface to a potentially inefficient postural control or sensory-motor feedback system may be detrimental (Brumagne et al., 2008; Della Volpe et al., 2006; Mok et al., 2004), and therefore account for the poor outcome observed in the rocker sole group.

Further research is required to determine whether brain directed treatment can influence CLBP. It is currently unknown as to whether the observed chemical and volume abnormalities within regions of the brain are reversible when pain has been reduced following conservative management. However, following surgical intervention in CLBP, dorsolateral prefrontal cortex abnormalities have been shown to be reversible (Seminowicz et al., 2011). For CLBP, mechanism-based treatments directed at influencing the dorso-lateral prefrontal cortex may be an effective management approach for CLBP.

10.6 Appropriateness of reassessment time points

Reassessment of CLBP participants at one year is accepted as 'long term' follow-up (Hayden et al., 2012; van Tulder et al., 2003), hence was deemed adequate for the assessment of participants in the main study. This trial duration is similar to that of previous research investigating CLBP rehabilitation (Cairns et al., 2006; Johnson et al., 2007; UK BEAM Trial Team, 2004).

The main aims of the biomechanical studies *(Chapter 7, p148 and 8, p170)* were to detect change in biomechanical parameters in the short (immediate) and long term (six months) following shoe use. Previous research investigating neuro-musculoskeletal and functional change during a one year exercise programme detected change in functional capacity at two months (Belardinelli et al., 1999) and in muscular activity at three months (Pyka et al., 1994), with changes maintained at one year follow-up. If footwear influenced the neuro-musculoskeletal system, it was anticipated that by six months, such changes should be established and maintained (assuming that shoes continued to be worn) enabling detection by the measures assessed.

10.7 Strengths and limitations

The main clinical study had 90% statistical power to detect clinically important change in the primary outcome measure, at the 0.05 significance level. This was in keeping with the recommendation that studies using multiple outcome measures should have a minimum power of 90% to detect change in the primary measures (Borm et al., 2006). The power of the biomechanical studies to detect change in kinematic, kinetic, or spatio-temporal variables cannot be assumed, and, although the sample sizes of the current biomechanical studies were as large or larger than most other biomechanical studies investigating similar outcomes in CLBP and asymptomatic individuals, it is possible that some type two errors may have occurred. However, baseline demographic data and pain and disability measures were similar between participants in the main study and biomechanical studies, as were changes in pain and disability at six weeks and six months. This suggests that those entering the biomechanical study were a representative sample of the main study, strengthening the ability to interrelate study conclusions, and to relate findings to the larger CLBP population.

10.8 Clinical relevance of these findings

This thesis suggests that wearing rocker sole shoes or flat sole shoes results in similar outcomes in the short and long term management of CLBP. However, if a person's pain is aggravated by standing or walking, rocker sole shoes may be detrimental to clinical improvement. These findings question whether proprioceptive rehabilitation programmes delivered in standing offer any training effect to the postural control system or clinical benefit to people with CLBP.

The current study investigated one brand of rocker sole shoe, hence caution must be taken when relating the current thesis findings to all brands of rocker sole shoes. However, considering the high proportion of similar between group findings in this thesis, it is unlikely that a different rocker sole brand would provide markedly different results.

It is not possible to compare the current studies with other research investigating footwear and CLBP due to a paucity of published research in this field. This paucity may exist due to a lack of research conducted; alternatively, conducted research may have demonstrated no improvement in CLBP, hence publication bias may be accountable. Either way, there is no evidence to indicate that footwear can positively influence CLBP in the short or long term. This is supported by a Cochrane review investigating the use of insoles in the prevention and treatment of back pain (Sahar et al., 2007).

10.9 Summary of further research

Potential future projects arising from this research process are listed:

- Research could be conducted to determine whether people reporting and not reporting pain during standing, walking, or other weight bearing activities respond differently to other physiotherapy interventions.

- Biomechanical studies should be conducted with an appropriately powered sample to determine whether postural control differences are present between people with mild, moderate and severe CLBP and asymptomatic individuals.

- The participants in the current biomechanical studies demonstrated, on average, similar postural control and stability to the asymptomatic individuals. It would be of interest to investigate CLBP participants with poor postural stability to determine whether 'balance training' programmes may influence postural stability in this population.

- There is no gold standard for assessing the relationship between the hip and ankle strategy. Reliability and validity of methods for determining the hip and ankle strategies and their relationship to each other in the maintenance of postural control could be investigated.

10.10 Conclusions

- Wearing a rocker sole or a flat sole shoe is likely to result in a similar clinical outcome at one year for people with CLBP.
- If a person's CLBP is predominately aggravated by standing or walking it may be more beneficial to wear a flat sole shoe than a rocker sole shoe.
- People with mild to moderate CLBP present with similar standing postural stability to people without CLBP.
- Long term wear of rocker sole shoes has no influence on postural control and stability in standing.
- Long term wear of rocker sole shoes has no influence on kinetic, kinematic and spatio-temporal parameters of gait.
- Proprioceptive rehabilitation delivered in standing is unlikely to improve postural stability in people with mild to moderate CLBP.
- Current therapies may be directed at influencing epiphenomena of CLBP.

11 Appendices

11.1 Contributors to thesis studies

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Chapter 3

Pilot study

JL conceived the study and was awarded funding. SM gained ethical approval, recruited study participants, conducted participant assessments and collected clinical data. JL acted as a co-researcher conducting aspects of the assessment of participants.

Reliability Study (published)

SM, JL, and MM contributed to the study design. SM and AvB obtained ethical approval. SM and AvB recruited participants. SM conducted participant assessments. SM and AvB contributed to statistical analysis. AvB drafted the study conclusions. SM, MM and JL contributed to critical revision of the published article. SM adapted published paper into PhD chapter format.

Chapter 4: Main Clinical Study

SM, JL, and MM contributed to the study design. SM gained ethical approval. SM recruited study participants. SM conducted participant assessments and collected clinical data. SM analysed study data following liaising with a King's College London statistician.

Chapter 6, 7 and 8: Biomechanical studies

SM conceived the biomechanical studies. AS contributed to study design. SM gained ethical approval. SM recruited and consented study participants. SM and AS conducted participant assessments. SM labelled and processed all standing and gait trials, identified gait cycle events, and extracted centre of pressure parameters from standing trials, and spatio-temporal, kinetic, and kinematic gait data. AS designed programmes for extraction of appropriate data. SM analysed study data. TF, AL, and JN assisted with gait laboratory calibration prior to participant assessments.

11.2 Oswestry disability questionnaire

Please read: This questionnaire has been designed to give the doctor information on how your back pain has affected your ability to manage in everyday life. Please answer every question, and mark only the one box in each Section that applies to you. While you may consider that two of the statements in any one section relate to you, please check just the one which most closely describes your situation.

Section 1- Pain Intensity

- ☐ I can tolerate the pain I have without having to use pain killers
- ☐ The pain is bad but I manage without taking painkillers.
- ☐ Painkillers give complete relief from pain.
- ☐ Painkillers give moderate relief from pain.
- ☐ Painkillers give very little relief from pain.
- ☐ Painkillers have no effect on the pain and I do not use them.

Section 2 – Personal Care (Washing, Dressing, etc)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally but it causes extra pain.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need some help everyday in most aspects of self-care.
- ☐ I do not get dressed, wash with difficulty, and stay in bed.

Section 3 – Lifting

- ☐ I can lift heavy weights without causing extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor. But I can manage if they are conveniently positioned, e.g., on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 – Walking

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than 1 mile.
- ☐ Pain prevents me from walking more than ½ mile.
- ☐ Pain prevents me from walking more than ¼ mile.
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 – Sitting

- ☐ I can sit still in any chair as long as I like.
- ☐ I can only sit in my favorite chair as long as I like.
- ☐ Pain prevents me from sitting more than 1 hour.
- ☐ Pain prevents me from sitting more than ½ hour.
- ☐ Pain prevents me from sitting more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing more than 1 hour.
- ☐ Pain prevents me from standing more than 30 minutes.
- ☐ Pain prevents me from standing more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 – Sleeping

- ☐ Pain does not prevent me from sleeping well.
- ☐ I can sleep well only by using tablets.
- ☐ Even when I take tablets I have less than 6 hours sleep.
- ☐ Even when I take tablets I have less than 4 hours sleep.
- ☐ Even when I take tablets I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8 – Sex Life

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9 – Social Life

- ☐ My social life is normal and gives no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interest, e.g., dancing etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to my home.
- ☐ I have no social life because of pain.

Section 10 – Traveling

- ☐ I can travel anywhere without extra pain.
- ☐ I can travel anywhere but it gives me extra pain.
- ☐ Pain is bad but I can manage journeys over 2 hours.
- ☐ Pain restricts me to journeys of less than 1 hour.
- ☐ Pain restricts me to short, necessary journeys less than 30 minutes.
- ☐ Pain prevents me from traveling except to the doctor or hospital.

OSWESTRY DISABILITY INDEX

____________________ ____________

Subject Signature   Date

11.3 Roland Morris disability questionnaire

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you *today*. As you read the list, think of yourself *today*. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember, only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that I usually do around the house.
5. Because of my back, I use a handrail to get upstairs.
6. Because of my back, I lie down to rest more often.
7. Because of my back, I have to hold on to something to get out of an easy chair.
8. Because of my back, I try to get other people to do things for me.
9. I get dressed more slowly than usual because of my back.
10. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.

13. My back is painful almost all the time.

14. I find it difficult to turn over in bed because of my back.

15. My appetite is not very good because of my back pain.

16. I have trouble putting on my socks (or stockings) because of the pain in my back.

17. I only walk short distances because of my back.

18. I sleep less well because of my back.

19. Because of my back pain, I get dressed with help from someone else.

20. I sit down for most of the day because of my back.

21. I avoid heavy jobs around the house because of my back.

22. Because of my back pain, I am more irritable and bad tempered with people than usual.

23. Because of my back, I go upstairs more slowly than usual.

24. I stay in bed most of the time because of my back.

Name: **Study number:**

Date when completing form:

SF-36 Health Survey

INSTRUCTIONS: This survey asks your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

When complete, please return the questionnaire in the envelope provided.

---

1. In general, would you say your health is:

		(circle one)
Excellent	....	1
Very good	....	2
Good	....	3
Fair	....	4
Poor	....	5

2. Compared to one year ago, how would you rate your health in general now?

		(circle one)
Much better now than one year ago	....	1
Somewhat better than one year ago	....	2
About the same as one year ago	....	3
Somewhat worse than one year ago	....	4
Much worse now than one year ago	....	5

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

(circle one number on each line)

Activities	Yes, limited a lot	Yes, limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	1	2	3
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
Lifting or carrying groceries	1	2	3
Climbing several flights of stairs	1	2	3
Climbing one flight of stairs	1	2	3
Bending, kneeling or stooping	1	2	3
Walking more than a mile	1	2	3
Walking half a mile	1	2	3
Walking one hundred yards	1	2	3
Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

(circle one number on each line)

	Yes	No
Cut down on the amount of time you spent on work or other activities	1	2
Accomplished less than you would like	1	2
Were limited in the kind of work or other activities	1	2
Had difficulty performing the work or other activities (for example, it took extra effort	1	2

5.During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

(circle one)

Not at all	....	1
Slightly	....	2
Moderately	....	3
Quite a bit	....	4
Extremely	....	5

7. How much bodily pain have you had during the past 4 weeks?

(circle one)

None	....	1
Very mild	....	2
Mild	....	3
Moderate	....	4
Severe	....	5
Very severe	....	6

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

(circle one)

Not at all	....	1
A little bit	....	2
Moderately	....	3
Quite a bit	....	4
Extremely	....	5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of life?	1	2	3	4	5	6
Have you been a very nervous person?	1	2	3	4	5	6
Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
Have you felt calm and peaceful?	1	2	3	4	5	6
Did you have a lot of energy?	1	2	3	4	5	6
Have you felt downhearted and low?	1	2	3	4	5	6
Did you feel worn out?	1	2	3	4	5	6
Have you been a happy person?	1	2	3	4	5	6
Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

(circle one)

All of the time 1
Most of the time 2
Some of the time 3
A little of the time 4
None of the time 5

11. How TRUE or FALSE is each of the following statements to you?

(circle one number on each line)

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get ill more easily than other people	1	2	3	4	5
I am as healthy as anybody I know	1	2	3	4	5
I expect my health to get worse	1	2	3	4	5
My health is excellent	1	2	3	4	5

11.5 Tampa scale of kinesiophobia

1 = strongly disagree
2 = disagree
3 = agree
4 = strongly agree

1. I’m afraid that I might injure myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. My pain would probably be relieved if I were to exercise	1	2	3	4
5. People aren’t taking my medical condition seriously enough	1	2	3	4
6. My accident has put my body at risk for the rest of my life	1	2	3	4
7. Pain always means I have injured my body	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous	1	2	3	4
9. I am afraid that I might injure myself accidentally	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	1	2	3	4
11. I wouldn’t have this much pain if there weren’t something potentially dangerous going on in my body	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I don’t injure myself	1	2	3	4
14. It’s really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can’t do all the things normal people do because it’s too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don’t think it’s actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain	1	2	3	4

11.6 Hospital anxiety and depression score

I feel tense or 'wound up':		**I feel as if I am slowed down:**	
Most of the time		Nearly all of the time	
A lot of the time		Very often	
Time to time, occasionally		Sometimes	
Not at all		Not at all	
I still enjoy the things I used to enjoy:		**I get a sort of frightened feeling like 'butterflies in the stomach':**	
Definitely as much		Not at all	
Not quite so much		Occasionally	
Only a little		Quite often	
Not at all		Very often	
I get a sort of frightened feeling like something awful is about to happen:		**I have lost interest in my appearance:**	
Very definitely and quite badly		Definitely	
Yes, but not too badly		I don't take as much care as I should	
A little, but it doesn't worry me		I may not take quite as much care	
Not at all		I take just as much care as ever	
I can laugh and see the funny side of things:		**I feel restless as if I have to be on the move:**	
As much as I always could		Very much indeed	
Not quite so much now		Quite a lot	
Definitely not so much now		Not very much	
Not al all		Not at all	
Worrying thoughts go through my mind:		**I look forward with enjoyment to things:**	
A great deal of the time		A much as I ever did	
A lot of the time		Rather less than I used to	
From time to time but not too often		Definitely less than I used to	
Only occasionally		Hardly at all	
I feel cheerful:		**I get sudden feelings of panic:**	
Not at all		Very often indeed	
Not often		Quite often	
Sometimes		Not very often	
Most of the time		Not at all	

I can sit at ease and feel relaxed:		**I can enjoy a good book or radio or TV programme:**	
Definitely		Often	
Usually		Sometimes	
Not often		Not often	
Not at all		Very seldom	

11.7 Pilot study participant information sheet

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Therapy Department

PARTICIPANT INFORMATION SHEET

V 1. 04/07/2007

1. Study title

Lower back pain: Can shoe type reduce the pain and recurrence rate?
RREC No: 07/H0706/74

Evidence exists that suggests footwear type may play a role in activating the small muscles of the back making them stronger and in doing so reduce back pain and the recurrence of repeated episodes of back pain.

2. Invitation paragraph

You are being invited to take part in a research study that is aiming to investigate the benefit of different footwear type in the treatment of lower back pain.

Before you decide to participate it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP, Consultant, or the Chief Investigator of the study, if you wish. Please ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part. There will be no difference in waiting times for your treatment if you decide that you do not wish to participate in this research study. Please let us know if you are currently participating or have recently participated in another research project. If you have, it may not be appropriate for you to consider participating in this study.

3. What is the purpose of the study?

Research studies have clearly shown that exercise and rehabilitation is beneficial for the majority of patients with lower back pain. Research also suggests that shoe type may be influential in force reduction in the spine improving muscle activation around the spine, and in doing so may further help to facilitate an improvement in outcome for patients with low back pain. There is, however very little guidance as to the best type of footwear to achieve these effects. Recommendations have included force reduction/shock absorption flat sole sport shoes, and force reduction/shock absorption rocker sole sport shoes (these are shoes that have a slight curve on their sole).

Although both shoe types are designed to reduce forces through the spine, it is not known as to which shoe type is more effective at doing this.

What we are aiming to achieve in this study is to determine if the addition of either a flat sole sport shoe, or a rocker sole sport shoe to traditional physiotherapy exercises and rehabilitation improves the outcome for patients with lower back pain.

4. Why have I been chosen?

Most probably you will be reading this document because you have lower back pain and will be offered a physiotherapy exercise programme for your pain as part of the normal treatment for your condition.

We are approaching you because we would like you to consider taking part in a research study that is being conducted in the physiotherapy department. The study will involve measuring the effectiveness of treatment in 2 different treatment groups for patients suffering with lower back pain. Group 1: Rocker sole sport shoes and exercise, and Group 2: Flat sole sport shoes and exercise.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form before the study starts. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or subsequent withdrawal will not affect the standard of care you receive.

5. What will happen to me if I take part?

Research studies have demonstrated that exercise therapy is very effective for the treatment of lower back pain. In the physiotherapy department we have developed a specialized group lower back pain rehabilitation group programme. The lower back pain rehabilitation programme in the physiotherapy department is normally 8 treatments, each of approximately 1 hour, over a 4 week period. This programme is given as a group treatment where you will be with up to 9 other people (10 in total) who are also suffering from lower back pain. This programme is run by two experienced physiotherapists. The group is a specialised programme and involves education, exercises and treatments based on current research evidence. In addition to attending the lower back rehabilitation class you will be requested to continue with the exercises at home. This is to maximize the benefit of the rehabilitation programme. We carefully select patients to participate in our group programme and certain people cannot participate. People with lower back pain who are ineligible to participate in the group get offered alternative treatment.

In this study we are aiming to compare whether the addition of rocker sole sport shoes or flat sole sport shoes when added to the lower back rehabilitation programme improves the outcome of treatment. As with most research investigations it would not be appropriate for certain people to participate for example, if you are pregnant, or if you have had surgery to you lower limbs in the past 12 weeks.

If you are eligible for both the rehabilitation programme and for the research study and you choose to participate in the research study, you will be asked to wear either rocker sole sport shoes or flat sole sport shoes during the period of time that you are involved in the rehabilitation programme (i.e. 4 weeks). You will be requested to gradually increase the amount you wear the shoes from 1 hour per day, to two hours per day to three hours per day etc, up to 5 hours per day. This is important because we are trying to determine which shoe type will have an increased effect on low back pain, and we need you to wear the shoes for this period of time. We will provide the shoes for you and you may keep the shoes after the study is complete. You will be required to document daily, the number of steps you have taken in the shoes. You will be provided with a diary to record your daily number of steps. The number of steps will be counted by a pedometer. You will also be asked to fill in an exercise diary on a daily basis.

Additional information

The lower back exercise class time is set at the same time each week. This is to facilitate a regular period of time between each class and to ensure all the necessary equipment and teaching information is available at each class. If you agree to participate you will be required to attend the hospital twice a week for a period of 4 weeks to attend the classes.

If you are eligible and choose to participate in this study you will be requested to complete a number of questionnaires about your lower back pain. These questionnaires take approximately 15 minutes to fill in and involve placing a tick or mark next to an answer that you feel is the most appropriate. We will also measure how much movement there is in your lower back. These are routine tests performed by all physiotherapists to assess the function of the lower back.

As this is a research study you will not be able to choose which group you will be in. This is to ensure that strict research standards are adhered to. If you agree to participate, and after you have had your first series of tests the chief investigator for the study will give you a sealed envelope to take to the physiotherapy reception desk. The group that you will join will be written on a folded piece of paper in the envelope. It is only at this time you will know which group you will be in. It will not be possible to change the group you are allocated to. You will then be fitted with either a pair of rocker sole sport shoes, or flat sole sport shoes. You will then be instructed how to walk effectively in the shoes, and hoe to use the pedometer, which will monitor the number of steps you take in the investigation period.

As this is a research investigation and we want to learn what is the most effective way to treat lower back pain, we will ask your permission to measure your lower back movements, amount of pain and to complete questionnaires on a further one occasion at the end of the 4 week exercise programme. This is to determine how the different treatments have affected you.

We will request that you allow us to measure your range of movement, pain levels and to complete questionnaires at the following times;

(1) Before you start the lower back rehabilitation programme.
(2) At the end of the 4 week lower back rehabilitation programme.

That is two times in total (each time should take no more than 30 minutes).These measurements will be made in a private treatment area. To make these measurements you will be asked to remove your shirt or top, and will be asked to wear a pair of shorts. Female participants will keep their bras on or if they choose may wear a singlet. If you wish you will be provided with a treatment gown.

During the course of your treatment hospital transport will be provided for anyone requiring this service who meets the Trusts transport regulations.

The following table summarises the required involvement for this study for those agreeing to participate and who are eligible to participate.

	Consent form signed and first assessment (15 minutes) Following this, group allocation determined, shoes fitted, and pedometer use explained. (30mins)	Treatment period (4 weeks in total)	Post treatment follow-up Immediately following your last hospital treatment,	**TOTAL NUMBER OF VISITS TO HOSPITAL**
Group 1: Specialised lower back rehabilitation group and rocker sole sport shoes	Yes	2 lower back rehabilitation groups per week of one hour for 4 weeks That is 2 hospital visits a week for 4 weeks.	Yes	10
Group 2: Specialised lower back rehabilitation and flat sole sport shoes	Yes	2 lower back rehabilitation groups per week of one hour for 4 weeks. That is 2 hospital visits a week for 4 weeks.	Yes	10

<u>Please note</u>: If you already know that you will not be able to attend the programme twice a week for four weeks we would request that you do not offer to participate. The reason for this is that all scientific investigations require that a certain number of people are followed for the entire time of the study. If there are not enough people at the end of the time period then the results of the study may not be of any meaning.

However, please remember that you are free not to participate and you are free to leave the study for whatever reason you choose at any stage. Your decision to leave the study will not affect the quality of care you receive.

It is important for you to know that there will be no difference in the waiting times for the lower back rehabilitation group for those agreeing to participate in this study and those not wishing to participate.

6. What do I have to do?

The first thing you need to do is decide if you would like to participate or not. This is entirely your decision and deciding not to participate will not affect the quality of your care. If you do decide to participate you will need to follow the procedure outlined in section 5.

7. What is the procedure that is being tested?

We are trying to determine if the addition of rocker sole sport shoes or flat sole sport shoes in addition to a specialised lower back rehabilitation exercise group, further helps to reduce pain and improve function.

We will be investigating this in a randomised clinical trial. This means that people participating in this trial will be randomly allocated into one of two groups; Group 1 (exercise and rocker sole sport shoes), and Group 2 (exercise and flat sole sport shoes). To ensure the scientific integrity of this investigation a computer programme will determine your group allocation. You will not be able to choose the group you are allocate to. You will have a 1 in 2 chance of being placed in the exercise and rocker sole shoe group (Group 1), and a 1 in 2 chance of being placed in the exercise and flat sole shoe group (Group 2).

8. What are the side effects of taking part?

Some participants may find the physical test (range of movement) for the lumbar spine produce some pain. In most cases this will be similar to the pain experienced in their back. The tests are used clinically to help determine which structure or structures are involved in their symptoms and are an essential part of the assessment procedure. We also perform these tests to see if you are improving as a result of the treatment you have received.

A subject walking in their new shoes may initially be aware of increased lower back pain. Subjects walking in these shoes may attain a slightly different posture than normal. This can lead to an increased activation of the lower back muscles. When muscles start to work harder they can be painful. This should normally resolve within a few days. Additionally, a burning sensation may be experienced by certain individuals whilst wearing new shoes. This is due to increased blood flow to the small muscles in the foot. This should settle after a few weeks. Sensations such as pins and needles, sweaty feet and numbness may occur initially and will subside after wearing their shoes.

Participants in the exercise group may also lead to an initial increase in discomfort. This is a well recognised phenomenon in any individual undertaking a new exercise programme and is known as delayed onset muscle soreness. It normally settles after a few days.

As with any new footwear, participants may develop blisters as a result of wearing either shoe type.

You may discuss any concerns you have with the clinical investigator, Siân MacRae on 020 8746 8404.

9. What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages or risks for those taking part in this study. The examination procedures and treatment procedures are ones used daily in physiotherapy clinics.

10. What are the possible benefits of taking part?

We do not currently know the most effective treatments for lower back pain and we hope that this research will help us understand the best way to treat this problem. However, as with all research, this cannot be guaranteed.

11. What if something goes wrong?

We do not anticipate for anything to go wrong in this study as we are not trying any new procedure, we are simply investigating the benefit of treatments people with lower back pain currently receive in a scientific manner.

However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms may be available to you.

12. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

If you do participate your GP (and Consultant if appropriate) will be sent a letter notifying them of your participation in this study (if you give your permission for this letter to be sent).

13. What will happen to the results of the research study?

We hope to use the information we obtain from this study to inform other health professionals about our results. We therefore ask your permission to publish the data we obtain. However, we guarantee to keep your name and identity confidential and this will not be made available to anyone at any stage. The results will probably be published about one year after the end of the study and if you are interested in finding out about our results, we would be happy to send you a one page summary of our findings.

14. Who is organising and funding the research?

This research is being organised by the Department of Physiotherapy at the Chelsea and Westminster Health Care NHS Trust. The provision of footwear is funded by a research grant from MBT Physiological Footwear.

15. Who has reviewed this study?

This study has been reviewed by external experts. In addition it has been reviewed by the Hospitals Research and Development Committee and the Riverside Research Ethics Committees.

16. Contact for further information

If you would like any further information about this study, please feel free to contact Siân MacRae, Senior Physiotherapist, on telephone number 020 8746 8404.

Additionally, if you are a patient and decide to participate in this research we will also ask you if you would like us to send a letter to your GP or consultant, informing them that you are participating in this study. We will also go through a series of screening questions to ensure that for ethical and healthcare reasons it is appropriate for you to participate in this study

17. After you have read this information sheet

If you think you would like to participate in this study please take time to think about your involvement. You might find speaking to family and friends and other healthcare professionals helpful. If you do decide to participate we will ask you to fill in and sign a Research Consent Form, in front of someone who will witness the signature.

If you agree to participate you will be given a copy of this information sheet and a copy of the consent form you signed. If you are a patient and do not wish to participate then your physiotherapist will organise a course of treatment for you.

Thank you for taking the time to read this information sheet.

11.8 Pilot and main study consent form

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Research Subject Consent Form

Title of Project: **Lower back pain: Can shoe type reduce the pain and recurrence rate?**

Protocol Version: Version … Date …………….

Local Research Ethics Number: R & D Registration Number:

Patient Hospital Number: Patient Study Identification Number:

Patient Initials:

Participant Declaration

	Please initial box if correct
I have been given the chance to read and understand the information sheet (dated …/…/…) relating to the above study	☐
I have been given the opportunity to ask questions and discuss the study.	☐
I have been made aware of the risks/ benefits	☐
I understand that authorised individuals may look at my medical notes and give permission for these individuals to have access	☐
I understand that I am free to withdraw from this study at any time without prejudice to my future care/ treatment	☐
I have had the compensation procedures explained to me	☐
I would like my GP or consultant to know that I am participating in this research project.	☐
I would like to receive a one page summary of the findings of this study.	☐

Title of Project: **Lower back pain: Can shoe type reduce the pain and recurrence rate?**

Local Research Ethics Number:

R & D Registration Number:

Patient Hospital Number:

I agree to take part in the above study

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

Person responsible for obtaining Informed Consent:
'To the best of my knowledge I have provided the above individual with sufficient information to enable them to give informed consent'.

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

Position ……………………………………………………………

Witnessed by:

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

11.9 Diary sheet

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

(first two pages only)

Therapy Department
Chelsea and Westminster Healthcare NHS Trust
Tel: +44 20 8746 8404 Email: sian.macrae@kcl.ac.uk

Research ParticipantsTraining Diary
Version …………….

Local Research Ethics Number: Patient Hospital Number: Patient Study Identification Number: Patient Initials:

	Date	No.of steps per day in study shoes	Times shoes worn per day (hrs:mins)	Form of Exercise session undertaken each day		Pain relief (analgesia)	
				Low back pain exercise group (Y/N)	Low back pain exercise session at home (hrs:mins)	Name of medication	Number of tablets and dose
Adaptation week							

	Date	No.of steps per day in study shoes	Times shoes worn per day (hrs:mins)	Form of Exercise session undertaken each day		Pain relief (analgesia)	
				Low back pain exercise group (Y/N)	Low back pain exercise session at home (hrs:mins)	Name of medication	Number of tablets and dose
WEEK 1							

11.10 EuroQol 5D-3L

Appendix 4.4 Euro-Qol-5D-3L

By placing a tick in one box in each group below, please indicate which statements
best describe your own health state today.

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐
I have some problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

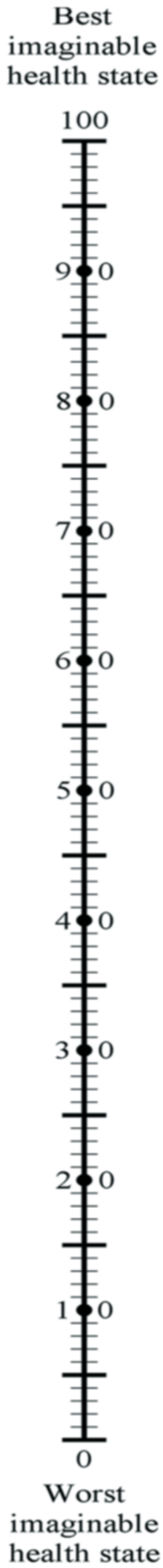
I am moderately anxious or depressed ☐

I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



11.11 Patient specific functional score

The Patient-Specific Functional Scale

This useful questionnaire can be used to quantify activity limitation and measure functional outcome for patients with any orthopaedic condition.

Clinician to read and fill in below: Complete at the end of the history and prior to physical examination.

Initial Assessment:

I am going to ask you to identify up to three important activities that you are unable to do or are having difficulty with as a result of your ________________ problem. Today, are there any activities that you are unable to do or having difficulty with because of your ________________ problem? (Clinician: show scale to patient and have the patient rate each activity).

Follow-up Assessments:

When I assessed you on (state previous assessment date), you told me that you had difficulty with (read all activities from list at a time). Today, do you still have difficulty with: (read and have patient score each item in the list)?

Patient-specific activity scoring scheme (Point to one number):

0	1	2	3	4	5	6	7	8	9	10
Unable to perform activity										Able to perform activity at the same level as before injury or problem

(Date and Score)

Activity	Initial					
1.						
2.						
3.						
4.						
5.						
Additional						
Additional						

Total score = sum of the activity scores/number of activities
Minimum detectable change (90%CI) for average score = 2 points
Minimum detectable change (90%CI) for single activity score = 3 points

PSFS developed by: Stratford, P., Gill, C., Westaway, M., & Binkley, J. (1995). Assessing disability and change on individual patients: a report of a patient specific measure. Physiotherapy Canada, 47, 258-263.

11.12 Patient satisfaction with study footwear

Extremely satisfied	☐
Very satisfied	☐
Somewhat satisfied	☐
Mixed (50/50)	☐
Somewhat unsatisfied	☐
Very unsatisfied	☐
Extremely unsatisfied	☐

11.13 Reliability of measuring thoracic kyphosis angle, lumbar lordosis angle and straight leg raise with an inclinometer

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Open Access

Reliability of Measuring Thoracic Kyphosis Angle, Lumbar Lordosis Angle and Straight Leg Raise with an Inclinometer

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Abstract: *Purpose:* Several non-invasive measurement methods have been described in the literature for recording thoracic kyphosis, lumbar lordosis and straight leg raise (SLR). However, attempts to quantify the reliability of the inclinometer in these measurements are scarce. In addition, existing reliability studies within the literature were found to use small sample sizes. The aim of this investigation was to examine the intra-rater reliability of the chief investigator (SM), in order to provide clinicians with data that will allow them to better measure sagittal spinal posture and SLR. A blinded test-retest design was performed to determine the intra-rater reliability of thoracic kyphosis, lumbar lordosis and SLR when assessed using an Isomed inclinometer in normals.

Methods. Thirty asymptomatic subjects were assessed on two occasions separated by a time interval of 1 hour to reduce investigator memory bias. Thoracic and lumbar measurements were recorded in a relaxed standing position using an inclinometer; SLR of the dominant leg was assessed with subjects in the supine position. Intraclass correlation coefficients (ICC), 95% confidence intervals (CI), and standard errors of measurement (SEM) were analysed to determine measurement reliability.

Results. The chief investigator demonstrated excellent intra-rater reliability in the measurements of thoracic kyphosis, lumbar lordosis and SLR. ICC (2,3) values for all three variables exceeded the 0.90 threshold suggesting that the reliability of these measures are acceptable for clinical application.

Conclusions. The inclinometer technique employed in this study to record thoracic kyphosis, lumbar lordosis and SLR is a reliable measurement method.

Keywords: Intra-rater reliability, lumbar lordosis, posture, straight leg raise, thoracic kyphosis.

INTRODUCTION

The evaluation of posture is commonly assessed to help guide diagnosis and plan treatment in musculoskeletal conditions [1, 2]. Two variables commonly assessed during an examination of spinal posture are thoracic kyphosis and lumbar lordosis. It has been suggested that deviations in one or both of these variables may increase a person's risk of developing low back pain [3-5]. In addition, the straight leg raise (SLR) test, which is used to stress neuromuscular structures, is a potential indicator of lumbar disc pathology [6], often becoming impaired during presentations of low back pain and sciatica [7].

Standing radiographs are the gold standard method for measuring spinal angles. The radiograph enables the traditional Cobb method, modified Cobb method, computer assisted method for deriving radius of thoracic spine curvature, and thoracic vertebral centroid angles to be calculated [8, 9]. The use of a simple, quick and reliable method for measuring both spinal angles and SLR would be beneficial in a clinical setting where radiographic investigations are not commonly indicated.

Since its inception in the late 1960's, inclinometry has received widespread attention by many authors who advocate its use in measuring both spinal posture [10-15] and SLR [16, 17]. Non-invasive measurement devices such as the inclinometer may help improve diagnostic accuracy and aid the clinician in determining a patient's progress more efficiently [11].

Despite the inclinometer's increasing popularity, reports detailing its reliability are scarce [15]. The fact that there have been negligible efforts to investigate the reliability of thoracic kyphosis, lumbar lordosis and SLR measurements using this tool in a clinical setting may result in a lack of validity of the outcome measures obtained from its use. Previous inclinometer studies have used small samples sizes [10, 17] and less robust reliability statistics [18]. Therefore, an investigation using a larger sample size, supported by appropriate reliability statistics is required. The aim of this study was to investigate the intra-rater reliability of measuring thoracic kyphosis angle, lumbar lordosis angle and SLR using an inclinometer in a clinical environment.

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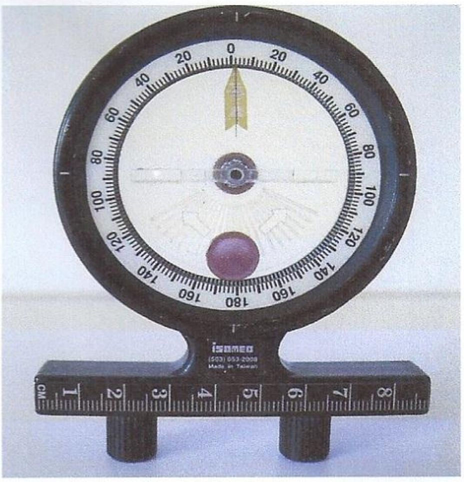

Fig. (1). Isomed Inclinometer.

The experimental hypothesis for this study was that the intra-rater reliability of the investigator measuring thoracic kyphosis angle, lumbar lordosis angle and SLR will show acceptable intraclass correlation coefficients (ICC = 0.91-1.00) indicating reliability suitable for clinical measurements [19].

MATERIALS AND METHODS

Subjects

This study was approved by a Research Ethics Subcommittee at King's College London [KCL]. Subjects were recruited via email advertising using the KCL website and by verbal invitation at the Guy's Campus at KCL. Male and female volunteers aged 18 to 65 years of age fulfilled the inclusion criteria. Exclusion criteria were any indication of lower limb neurological compromise, or a history of thoracic pain, lumbar pain, or lower limb disorders over the past six months requiring medical attention. Limitation of movement of the hip or knee, scoliosis, chest conditions such as asthma, chronic bronchitis and emphysema, pregnancy, any systemic illness, and an inability to give informed consent were also criteria for exclusion.

Procedure

All testing was conducted in the same room at KCL by the chief investigator (SM). Those individuals who agreed to participate and met the inclusion criteria and did not fulfil the exclusion criteria were invited to attend two appointments, approximately one hour apart. On the first appointment subjects were given a full explanation of the testing procedure, warned of any potential risk factors and asked to sign informed consent documentation by the second investigator (AVB). Body mass, height and age were recorded.

Prior to measuring spinal angles, participants were asked to stand with their feet either side of a spot marked on the floor (to ensure standardisation of subject position between measures) and adopt a comfortable standing position that felt natural to them. The spinous processes of T1/T2, T12/L1 and S2/S3 were then identified by palpation and marked with six millimetre diameter non-allergenic adhesive stickers. The palpation techniques employed in this study were adapted from those described by Palastanga *et al.* [20]. Three inclinometer (Isomed Unilever) measurements (Isomed, 975 Sandy Blvd., Portland, OR 97214) were then taken from each marker location. The inclinometer Fig. (**1**) consists of a perspex protractor with a freely swinging pointer, and two feet which project from its base. The pointer is gravity-dependent and reads the angle tangent to the surface being measured. Mean values were summated, using the linear & triangular addition of angles rule [12], for T1/T2 and T12/L1 measurements and T12/L1 and S2/S3 measurements to acquire the thoracic kyphosis Fig. (**2**) and lumbar lordosis angle, respectively.

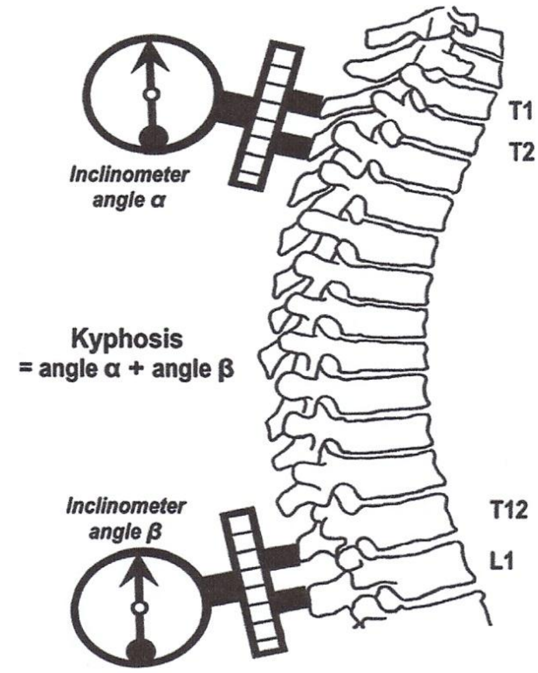

Fig. (2). Angle for measuring thoracic and lumbar spine angles.

On completion of the standing measurements, subjects were asked to lie supine on a plinth with a pillow under their head, arms by their sides, no lateral flexion or rotation at their trunk, and hips in neutral adduction/abduction. An adhesive marker was then placed directly on the subject's tibial tuberosity of their dominant [test] leg [determined by asking each subject which leg they would kick a football with]. During the SLR test, the subject's contralateral knee was stabilised by one of the two examiners in an attempt to reduce spinal movement. Three inclinometer readings, representing SLR, were taken by placing the apparatus over the marker [17]. The end point of the SLR movement was determined when the subject reported the first onset of either stretch or discomfort.

All stickers were removed after the first measurement session. The interval between appointments was one hour ensuring that the chief investigator could not recall previous measurements. To further reduce investigator memory bias, the data collection procedure was staggered with two other subject data collections filling the time between another

Table 1. Subject Demographics

Variables	Subjects (n=30)
Age (years)	33 (SD +/-11.23)
Body height (cm)	172 (SD +/- 11)
Body mass (kg)	72 (SD +/- 12)
Gender	Male: 15 (50%) Female: 15 (50%)
Dominant Leg	Right: 27 (90%) Left: 3 (10%)

subject's first and second visits. This meant that a total of 18 measurements were recorded before the second set of measurements were made on the initial subject.

Sample Size Estimation

For a significance level of 5% and a power of 80, the suggested adequate number of subjects required is 19 [21, 22]. The number of subjects recruited into the current study was increased to 30 in order to increase statistical power, and to account for a loss of subject data and subject withdrawal.

Statistical Analysis

Mean values of each measurement recorded were used for data analysis. Intra-rater reliability was determined by means of intraclass correlation coefficients (ICC), 95% confidence intervals (95% CI) and standard error of measurements (SEM) [23]. ICC model 2 has been suggested [19] to be best suited for generalizing the findings to clinicians with similar clinical experience. ICC models for single measures (2,1) and for average measures (2,3) were evaluated using SPSS version 17.0 software [SPSS Inc., Chicago, Il, USA]

RESULTS

A total of 30 asymptomatic subjects (15 female, 15 male) were recruited for this study. Subject demographic data is presented in Table **1**. The ICC, 95% CI and SEM for the spinal and SLR measurements are presented in Table **2**. The ICC Model (2,1) results for the single measurements ranged

Table 2. Intra-rater Reliability Results

		Thoracic Kyphosis (T1/2 + T12/L1)	Lumbar Lordosis (T12/L1 – S2/3)	Straight Leg Raise
Mean (°)	Test 1	32 (SD +/-8)	-29 (SD +/-8)	80 (SD +/-12)
	Test 2	33 (SD +/- 8.1)	-29 (SD +/- 8)	81 (SD +/- 12)
Range (°)	Test 1	17 – 48	-50 - (-14)	59 – 104
	Test 2	16 – 48	-52 - (-13)	59 – 105
Single Measure ICC (2,1)		0.92	0.79	0.94
95% CI for ICC (2,1)		0.84 – 0.96	0.60 – 0.90	0.88 – 0.97
SEM (°) for ICC (2,1)		2.3	3.8	3.0
2 x SEM (°) for ICC (2,1)		4.6	7.7	5.9
Average Measures ICC (2,3)		0.96	0.93	0.98
95% CI for ICC (2,3)		0.92 – 0.98	0.83 – 0.97	0.96 – 0.99
SEM (°) for ICC (2,3)		1.7	2.3	1.7
2 x SEM (°) for ICC (2,3)		3.3	4.6	3.5

Legend: SD Standard deviation
ICC Intra-class correlation coefficient
CI Confidence interval
SEM Standard error of measurement

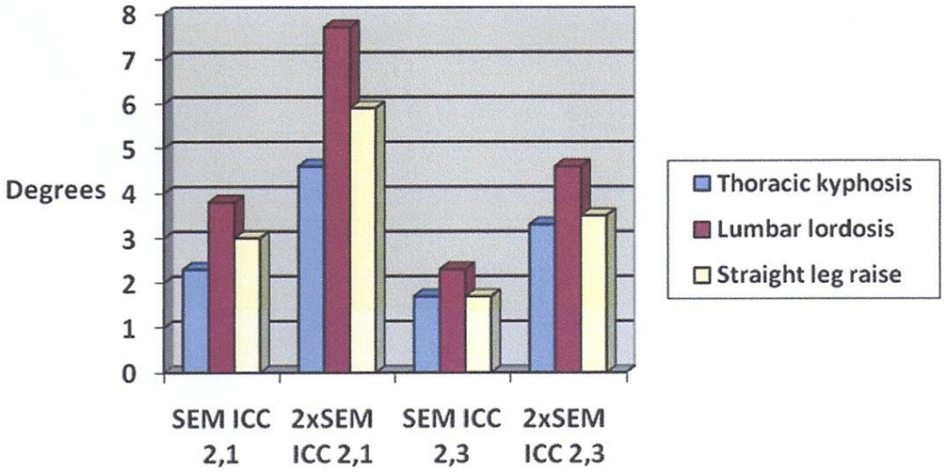

Fig. (3). SEM and 2xSEM values.

from 0.79 to 0.94, and for average measures [ICC Model (2,3)] ranged from 0.93 to 0.98.

Thoracic kyphosis, lumbar lordosis and SLR measures all showed ICC's > 0.75 for ICC (2,1) and ICC (2,3) measurements, thus indicating good overall reliability [19]. The ICC average measures (2,3) demonstrated agreement above 0.90 for all three variables. Most notably, SLR demonstrated the best ICC out of all measures with 0.94 for the single ICC (2,1) and 0.98 for the average ICC (2,3) measures. In addition, thoracic kyphosis and lumbar lordosis angle scored highly using the standards of agreement described by Portney & Watkins [19], with average measure ICC's equating to 0.94 and 0.93, respectively. For the average measures, the 95% CI for SLR, thoracic kyphosis and lumbar lordosis (Table **2**) all show relatively narrow boundaries indicating a small margin of error in the application of this technique [24].

The SEM, a reflection of the degree of error associated with a particular method of measurement [19], demonstrated 1 SEM values of 2° for thoracic kyphosis, lumbar lordosis and the SLR Fig. (**3**). Using the 1 SEM, a clinician may assume with 68% certainty that the individuals true score will lie between +/-2° of the measured value if the clinician's skill matches the examiner in this study. When examining the 2 SEM scores, which increase the certainty to 95%, these values increase to approximately 4°. Therefore, the minimal value required for these measures to be considered real change is 4°.

DISCUSSION

The primary focus of this study was to evaluate the intra-rater reliability of clinical methods for measuring thoracic kyphosis, lumbar lordosis and SLR. Analysis of the results obtained in this study suggest that the technique employed by the chief investigator demonstrated reliability acceptable for clinical application [19].

At present, a limited number of investigations have assessed the intra-rater reliability of thoracic kyphosis, lumbar lordosis or SLR. Furthermore, no studies have been identified that assess a single investigator's reliability when measuring all three variables as part of a continuous assessment procedure that replicates clinical practice. In order to validate the external measurement techniques undertaken in this study, comparisons have been made between results of this investigation and those found in the literature.

THORACIC KYPHOSIS

As part of a larger investigation examining shoulder impingement syndrome, Lewis and colleagues [10] performed a pilot study to test the measurement reliability of the chief investigator. In the asymptomatic group, Lewis *et al.* [10] demonstrated single measurement ICC (2,1) scores for thoracic kyphosis of 0.96, 95% CI from 0.91 – 0.98, and +/-1 SEM of 2°. These results are in strong agreement with those of the current study which demonstrated good reliability for both single [ICC (2,1) = 0.92; 95% CI = 0.84 – 0.96; and 1 SEM = 2°] and average [ICC (2,3) = 0.96; 95% CI = 0.92 – 0.98; and 1 SEM = 2°] measures. Although 30 subjects were tested by Lewis *et al.* [10], the symptomatic (n = 15) and asymptomatic (n = 15) groups were examined independently. It has been suggested that 19 subjects would be adequate to determine true instrument reliability [21]. For this reason, subject numbers used in the Lewis *et al.* investigation [10] may not have been sufficient in comparison to the larger sample size used in the current study.

In addition to the Lewis *et al.* [10] findings, Mellin [11] demonstrated similar intra-rater ICC values of 0.92 when measuring the kyphosis of asymptomatic subjects (n =10). Unfortunately, this author does not describe in detail which mathematical method was used to calculate the thoracic angle, thus making it difficult for comparisons to be made with the current investigation. In accordance with Sim and Wright's [22] suggested subject sample size of 19, the ten subjects in Mellin's study may not have been sufficient to fully determine the reliability of the technique. However, even with this reduced sample size, similar ICC values to that of our larger study were obtained.

LUMBAR LORDOSIS

Mellin [11] reported similar ICC values (0.94) to the current study for postural lordosis, however, there is no reference to the ICC model that was used. Agreement between these two findings may relate to similar subject positioning as both studies measured spinal curvatures in neutral standing. In a more recent study, Ng *et al.* [15] measured lumbar angles in combination with lumbar range of movement on 12 healthy men with no history of back pain. The ICC results for lumbar lordosis were 0.95, suggesting that the method of measurement employed by Ng and colleagues [15] showed adequate clinical reliability [19]. However, even though their score is similar to that achieved in the present study, it should not be construed as a definitive clinical representation of reliability. These authors did not calculate the 95% CI or SEM, which help to indicate the magnitude of disagreement between measurements, or indicate which ICC model was used for analysis.

The results of the present study also lend support to the findings of Norton *et al.* [25] who measured the lumbar curvature of 30 adults using the Metrecom and a bubble goniometer. Norton *et al.* [25] demonstrated an ICC (3,3) of 0.92. Similarities in the ICC scores are thought to be due to a number of reasons. Firstly, the methods employed in both investigations utilise the tangent mathematical model as described by Loebl [12]. Secondly, both Norton *et al.* [25] and the investigators in the current study recorded lumbar lordosis from the spinous processes of T12/L1 and S2.

SLR

Excellent intra-rater reliability [ICC (2,3) = 0.98; 95% CI = 0.96 – 0.99; and 2 SEM = 4°] was shown in the current investigation when measuring SLR. These findings are comparable with those shown in one previous study by Li *et al.* [26] who demonstrated an ICC of 0.99 when using an inclinometer to record SLR using a similar method. Conversely, inclinometer readings for a SLR reliability pilot study by Corben *et al.* [17] showed good levels of reliability with an ICC of 0.87, 95% CI of 0.56 – 0.97, and SEM of 3° [17]. Of particular interest is that both Corben *et al.* [17], and the investigators in the current study measured SLR with the Isomed inclinometer placed over the tibial tuberosity of the testing leg. However, despite similarities in the testing procedure, reliability results were considerably different. This can be attributed to a number of factors. Firstly, when testing SLR the present study fixed the thigh of the non-tested leg to the bed using a second examiner. Another possible reason for the differences in findings was that Corben *et al.* [17] rested the opposite limb on pillows which may have reduced the specificity of the test. Additionally, these investigators used a small sample size (n = 10) to examine SLR reliability.

LIMITATIONS

Postural variation resulting from respiration and postural sway may have led to a degree of error during the measurement procedure. In addition, potential inaccuracies on palpation of anatomical landmarks may have affected the validity of the measurement. Subjects included in this study were 30 asymptomatic adults. Therefore, generalization of these results to individuals who are older or symptomatic would not be appropriate.

CLINICAL IMPLICATIONS

Current methods of measurements for idiopathic scoliosis include radiographic and stereovideographic techniques which can be both expensive and time consuming [27]. Therefore, the use of a simple, quick and reliable method for quantifying modifications in postural geometry would be valuable to clinicians who assess patients presenting with conditions like Ankylosing Spondylitis and Scheuermann's disease. The values obtained from the spinal measurements described in this study could also be used by clinicians providing feedback to patients when educating them on good postural positioning. Although this study demonstrates high reliability for the inclinometer assessment techniques, it does not demonstrate their validity as measures of spinal curvature. In order to establish validity, further research, comparing spinal angles obtained from inclinometer assessment with those obtained from radiographic investigations – the gold standard – is required.

CONCLUSION

The methods employed in this study have demonstrated excellent clinical reliability (ICC > 0.90) whilst using an Isomed inclinometer to measure thoracic kyphosis, lumbar lordosis and SLR in asymptomatic subjects. Advantages associated with this reliable method of measurement are that it is simple to use, time efficient, and relatively inexpensive to maintain. These positive characteristics lend further support to the use of this instrument within clinical practice, and should give therapists confidence when using this method of measurement to help guide treatment progression. The findings of this study compare favourably with previous studies, especially as this was one of the first investigations to utilise both a larger sample size and appropriate reliability statistical analyses.

CONFLICT OF INTEREST

The authors confirm that this article content has no conflicts of interest.

ACKNOWLEDGEMENT

Declared none.

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11.14 Reliability study ethical approval letter

Dr Matt Morrissey
Physiotherapy Division
School of Biomedical Sciences
Shepherd's House
Guy's Campus
King's College London
London SE1 1UL

18 June 2009

Dear Matt

BDM/08/09-85 Thoracic Kyphosis Angle, Lumbar Lordosis Angle and Hamstring Length: A Reliability and Correlation Study

Thank you for sending in the amendments requested to the above project. I am pleased to inform you that these meet the requirements of the BDM and therefore that full approval is now granted provided that the following changes are made in the information sheet and a copy of the amended information sheet is submitted for our records:

1. State that anonymised data is shared with other researchers.
2. Replace the last two sentences under the heading 'What are the possible disadvantages and risks of taking part?' with the following: We will check for any leg pain. When you first become aware of any such sensations, let us know and your leg will be returned to the start position.

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/attachments/good_practice_May_08_FINAL.pdf).

For your information ethical approval is granted until 18/06/2010. If you need approval beyond this point you will need to apply for an extension to approval at least two weeks prior to this explaining why the extension is needed, (please note however that a full re-application will not be necessary unless the protocol has changed). You should also note that if your approval is for one year, you will not be sent a reminder when it is due to lapse.

If you do not start the project within three months of this letter please contact the Research Ethics Office. Should you need to modify the project or request an extension to approval you will need approval for this and should follow the guidance relating to modifying approved applications: http://www.kcl.ac.uk/research/ethics/applicants/modifications.html

Any unforeseen ethical problems arising during the course of the project should be reported to the approving committee/panel. In the event of an untoward event or an adverse reaction a full report must be made to the Chairman of the approving committee/review panel within one week of the incident.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (http://www.kcl.ac.uk/research/ethics/contacts.html). We wish you every success with this work.

With best wishes

Yours sincerely

Riina Heinonen – Research Ethics Officer

For and on behalf of

Professor Tim Newton, Chairman

Biomedical and Health Sciences, Dentistry, Medicine and Physical Sciences & Engineering Research Ethics Subcommittee

11.15 Reliability study recruitment email

Research Study – Thoracic Kyphosis Angle, Lumbar Lordosis Angle and Hamstring Length: A Reliability and Correlation Study

This project contributes to the College's role in conducting research, and teaching research methods. You are under no obligation to reply to this email, however, if you choose to, participation in this research is voluntary and you may withdraw at any time.

We would like to invite you to participate in a postgraduate physiotherapy research project. We are looking for male or female volunteers aged 18 to 65 to take part in the above study being carried out at King's College London. You are not suitable to take part if you have any indications of lower limb neurological compromise, limitation of hip and knee movement, systemic illness, abnormal hamstring tightness, history of thoracic pain, back pain, or lower limb problems over the past six months that required medical attention.

This study aims to determine the intrarater reliability of the chief investigator in the study entitled 'Low Back Pain: Can Footwear Influence the Pain and Recurrence Rate.' (REC No: H0706/04), measuring thoracic kyphosis angle using an Isomed Unilevel inclinometer (Isomed, 975 Sandy Blvd., Portland, OR 97214). It also aims to establish if a correlation exists between between thoracic kyphosis angle, lumbar lordosis angle and hamstring length which may offer explanations for potential findings in the low back pain clinical study. Participation will involve you attending Guy's Campus, King's College London at a mutually convenient time twice, at least one hour apart, for approximately 20 minutes each time. To protect your modesty, all data will be collected in a quiet room.

On the first appointment you will be given a full explanation of the testing procedure and warned of any potential risk factors that may occur. You will then be asked to sign and date the consent form. During the data collection process, you will be expected to wear a pair of shorts. Male volunteers will be asked to remove their shirts, and female volunteers asked to undress down to vest tops or open-backed bathing suits. You will be asked to stand in a comfortable position on a spot marked on the floor. Non-allergenic adhesive markers will then be placed on three sites along your spine. Measurements will then be taken from these markers using the inclinometer to record the angle of your middle spine and lower back. On completion of the standing measurements, you will be asked to lie down on your back on a plinth. Another non-allergenic adhesive marker will be placed just below the knee of the test leg. Your leg will be lifted passively in a straightened position until your pelvis begins to move. A measurement using the inclinometer will then be taken at this point and hamstring length recorded.

In accordance with the Data Protection Act, all data will be handled with confidentiality and there will be no personal or medical details recorded. If you would like more information, please contact either Andrew Van Blommestein or Sian MacRae on the contact details below. You will then be sent the information sheet for the study containing further details of the procedure. An appointment will also be arranged to confirm your suitability for the study and give you the opportunity to ask any questions prior to agreeing to take part.

Thank you for your time and interest,

Kind Regards,

Andrew Van Blommestein
Student in MSc in Advanced Neuromusculoskeletal Physiotherapy
Student, MSc graduate
King' s College London
andrew.van_blommestein@kcl.ac.uk

Sian MacRae
Chief Investigator, PhD
sianmacrae@hotmail.com

11.16 Reliability study participant information sheet

REC Reference Number: BDM/08/09-85

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Thoracic Kyphosis Angle, Lumbar Lordosis Angle and Hamstring Length: A Reliability and Correlation Study.

We would like to invite you to participate in a postgraduate research project which is being conducted as part of an MSc in Advanced Neuromusculoskeletal Physiotherapy. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
To investigate the ability of the researcher (Sian MacRae) to reliably measure the angle of the curve in your upper back (your thoracic spine), the curve on your lower back (lumbar spine) and the length of the muscle in the back of your thigh (the hamstring muscle) using an inclinometer (an instrument for measuring the angle of an object).

Who are we recruiting to participate in this study?
We are recruiting healthy volunteers between 18 and 65 years of age with no recent back or lower limb injuries. People who fulfil any of the following criteria are unable to participate in this study: any indication of lower limb neurological compromise, history of thoracic pain, lower back pain, or lower limb problems over the past six months that required medical attention, limitation or movement at the hip or knee, scoliosis, chest conditions such as asthma, chronic bronchitis and emphysema, disease of the peripheral or central nervous system, pregnancy, any systemic illness, abnormal tightness of the hamstrings, or are unable to give consent.

Do I have to take part?
No. It is up to you to decide whether to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do decide to take part you will be given this information sheet to keep and asked to sign a consent form.

What happens if I choose to take part?
You will be asked to attend Guy's Campus, King's College London at a mutually convenient time twice, at least one hour apart, for approximately 20 minutes each time. To protect your modesty, all data will be collected in a quiet room.

On the first appointment you will be given a full explanation of the testing procedure and warned of any potential risk factors that may occur. You will then be asked to sign and date the consent form.

During the data collection process, you will be expected to wear a pair of shorts. Male volunteers will be asked to remove their shirts, and female volunteers asked to undress down to vest tops or open-backed bathing suits.

You will be asked to stand in a comfortable position on a spot marked on the floor. Non-allergenic adhesive markers will then be placed on three sites along your spine. Measurements will then be taken from these markers using the inclinometer to record the angle of your middle spine and lower back.

On completion of the standing measurements, you will be asked to lie down on your back on a plinth. A pillow will be placed under the knee not being tested. Another non-allergenic adhesive marker will be placed on bare skin just below the knee of the test leg. Your leg will be lifted passively in a straightened position until your pelvis begins to move. A measurement using the inclinometer will then be taken at this point and hamstring length recorded.

Each measurement will be recorded three times on both the initial and subsequent appointment (1 hour later). The test procedure will remain unchanged on both visits. The second test will last for approximately 20 minutes.

If you do decide to take part, please let us know beforehand if you have been involved in any other study during the last year.

What are the possible disadvantages and risks of taking part?

There is a small risk of discomfort during the hamstring length test which may be felt as tightness, stretching or pulling sensations in the back of the leg. This is a normal, reversible consequence of performing the straight leg raise procedure. Participants will be informed of these potential effects and any leg pain will be monitored. We will check for any leg pain. When you first become aware of any such sensations, let us know and your leg will be returned to the start position.

If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

Dr Matt Morrissey
Division of Applied Biomedical Research
School of Biomedical and Health Sciences
Room 3.18, Shepherd's House
King's College London
London
SE1 1UL
Tel: 0207 848 6678
Email: matt.morrissey@kcl.ac.uk

What will happen to the information collected?

All information collected during the course of research will be kept strictly confidential i.e. in a locked filing cabinet and stored on a dedicated, password protected computer. Any information we obtain from you will have your name removed and will be numerically coded so that you remain anonymous. Only the researchers and the research supervisor will have access to the anonymised data which may be shared with other researchers. The results of the study may be published in medical journals or presented at medical conferences. Copies of the results can be obtained from the study organiser (Dr Matt Morrissey) when the study is completed.

You may withdraw from the study at any time without giving a reason. Data provided by participants, for the purpose of screening, who do not then proceed with the study will be destroyed immediately.

What are the possible benefits of taking part?
There will be no expected benefits to the participants in this study.

Thank you for reading this information sheet.

If you would like more information, please contact:
Andrew Van Blommestein MCSP
Chartered Physiotherapist/ MSc Student
Tel: 0207 848 6678
Email: andrew.van_blommestein@kcl.ac.uk

Sian MacRae
Chief Investigator/ MSc Graduate/ PhD Student
Email: sian.macrae@kcl.ac.uk

11.17 Reliability study consent form

King's College London
University of London

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: **Thoracic Kyphosis Angle, Lumbar Lordosis Angle and Hamstring Length: A Reliability and Correlation Study.**

King's College Research Ethics Committee Ref: BDM/08/09-85

- **(i)** **Thank you for considering taking part in this research. The person organizing the research must explain the project to you before you agree to take part.**
- **(ii)** **If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.**
- ***(iii)*** ***I understand that if I decide at any other time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately.***
- ***(iv)*** ***I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998.***
- ***(v)***

Participant's Statement:

I ____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed **Date**

Investigator's Statement:

I ____

confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the volunteer.

Signed **Date**

11.1

Riverside Research Ethics Committee
Room 4W/12, 4th Floor West
Charing Cross Hospital
Fulham Palace Road
London W6 8RF
Telephone: 020 8846 7282
Facsimile: 020 8846 7280

Miss Sian MacRae
Research Physiotherapist
King's College London
School of Biomedical&Health Science
PhD Office, Room SH 3.11
Shepherd's House, Guy's Campus
SE1 1UL

05 February 2009

Dear Miss MacRae

Full title of study:	**Low back pain: Can shoe type reduce the pain and recurrence rate?**
REC reference number:	**09/H0706/4**

Thank you for your letter of 28 January 2009, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Confirmation of approval for other sites listed in the application will be issued as soon as local assessors have confirmed they have no objection.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

<u>Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.</u>

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Response to Request for Further Information		28 January 2009
Participant Information Sheet	2	28 January 2009
Sample Diary/Patient Card	2	28 January 2009
Participant Flow Chart	1	20 November 2008
Participant Assessment Sheet	1	20 November 2008
Key Collaborator's CV		19 November 2008
Supervisor's CV		02 December 2008
Participant Consent Form	1	20 November 2008
GP/Consultant Information Sheets	1	20 November 2008
Advertisement	1	20 November 2008
Covering Letter		03 December 2008
Protocol	1	20 November 2008
Investigator CV		20 November 2008
Additional Medical Input	1	20 November 2008
Questionnaire: Pre Study Screening	1	20 November 2008
Questionnaire: Functional Scale		
Questionnaire: EQ-5D		
Questionnaire: HADS		
Questionnaire: Tampa Scale for Kinesiophobia		
Questionnaire: Roland-Morris Disability		
Application		28 November 2008
Letter from Supervisor		10 December 2008
Peer Review		25 September 2007

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review –guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

09/H0706/4	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

PP

Sabita Uthaya
Chair

Email: atul.patel@imperial.nhs.uk

Enclosures: *"After ethical review – guidance for researchers"*
Site approval form

Copy to: *Mr Keith Brennan*

Riverside Research Ethics Committee

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	09/H0706/4	**Issue number:**	1	**Date of issue:**	05 February 2009
Chief Investigator:	Miss Sian MacRae				
Full title of study:	Low back pain: Can shoe type reduce the pain and recurrence rate?				

This study was given a favourable ethical opinion by Riverside Research Ethics Committee on 05 February 2009. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* [1]
Miss Sian MacRae	Senior Musculoskeletal Physiotherapist	Chelsea and Westminster Hospital NHS Foundation Trust	Riverside Research Ethics Committee	05/02/2009	

Approved by the Chair on behalf of the REC:

.... (Signature of ~~Chair~~/Co-ordinator)

(delete as applicable)

Atul Patel.................. (Name)

11.19 Main study screening questionnaire

Participants name: Hospital Number:
DOB:

Statement: Most research projects recommend that certain patients don't participate in a specific study. This is usually for ethical or medical reasons. We will ask everyone participating in this study the following questions.

Are you younger than 18 years of age?	Yes	No
Are you older than 65 years of age?	Yes	No
Are you pregnant, suspect you are pregnant, or attempting to become pregnant?	Yes	No
Do you have any difficulty reading, writing, or communicating in English?	Yes	No
Have you had any treatment for your low back pain including: physiotherapy, osteopathy, chiropractic, injections, surgery in the past 12 months?	Yes	No
Is there any reason why you would not be able to attend an exercise class?	Yes	No
Are you involved in any ongoing litigation regarding your back pain?	Yes	No
Have you ever worn rocker sole trainers?	Yes	No
Have you been involved in a research study in the past 12 months involving any musculoskeletal pathology especially the lower back?	Yes	No

Have you been diagnosed with ANY of the following:

• Constant pain?	Yes	No
• Known spondylolysthesis?	Yes	No
• Severe structural deformity?	Yes	No
• Severe osteoporosis?	Yes	No
• Fracture of the spine within the last year?	Yes	No
• Inflammatory disease of the spine?	Yes	No
• Spinal infection?	Yes	No
• Spinal stenosis?	Yes	No
• Pins and needles, numbness or generalised weakness in your legs?	Yes	No
• Severe cardiovascular disease?	Yes	No
• Severe metabolic disease?	Yes	No
• Previous spinal surgery?	Yes	No
• Surgery to the lower limb in the past 8 weeks?	Yes	No
• Diagnosed tumour?	Yes	No
• Peripheral neuropathy?	Yes	No
• Morton’s Neuroma?	Yes	No
• Skin ulcerations over the foot?	Yes	No
• History of unexplained falls?	Yes	No
• Recent Deep Vein Thrombosis (DVT)?	Yes	No

Name: Signature: Date:

11.20 Main study participant information sheet

Chelsea and Westminster Hospital NHS

NHS Foundation Trust

1 .PARTICIPANT INFORMATION SHEET

V 2. Date 28.01.2009

2. Study title

Low back pain: Can shoe type reduce the pain and recurrence rate?
RREC No: 09/H0706/4

Evidence exists that suggests footwear type may play a role in activating the small muscles of the back making them stronger and in doing so reduce back pain and the recurrence of repeated episodes of back pain.

3. Invitation paragraph

You are being invited to take part in a research study that is aiming to investigate the benefit of different footwear types in the treatment of low back pain.

Before you decide to participate it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP, Consultant, or the Chief Investigator of the study, if you wish. Please ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part. There will be no difference in waiting times for your treatment if you decide that you do not wish to participate in this research study. Please let us know if you are currently participating or have recently participated in another research project. If you have, it may not be appropriate for you to consider participating in this study.

4. What is the purpose of the study?

Research studies have clearly shown that exercise and rehabilitation is beneficial for the majority of patients with low back pain. Research also suggests that shoe type may be influential in reducing the stresses that pass up through the spine, improving muscle activation around the spine, and in doing so may further help to facilitate an improvement in outcome for patients with low back pain. There is, however very little guidance as to the best type of footwear to achieve these effects. Recommendations have included flat sole sport shoes, and rocker sole sport shoes (these are shoes that have a slight curve on their sole). Although both shoe types are designed to reduce forces through the spine, it is not known as to which shoe type is more effective at doing this.

What we are aiming to achieve in this study is to determine if the addition of wearing either a flat sole sport shoe or a rocker sole sport shoe to traditional physiotherapy exercises and rehabilitation improves the outcome for patients with low back pain.

5. Why have I been chosen?

Most probably you will be reading this document because you have low back pain and will be offered a physiotherapy exercise programme for your pain as part of the normal treatment for your condition.

We are approaching you because we would like you to consider taking part in a research study that is being conducted in the physiotherapy department. The study will involve measuring the effectiveness of treatment in 2 different treatment groups for patients suffering with lower back pain. Group 1: Rocker sole sport shoes and exercise, and Group 2: Flat sole sport shoes and exercise.

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form before the study starts. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or subsequent withdrawal will not affect the standard of care you receive.

8. What will happen to me if I take part?

Research studies have demonstrated that exercise therapy is very effective for the treatment of low back pain. In the physiotherapy department we have developed a specialized low back pain rehabilitation programme. The low back pain rehabilitation programme in the physiotherapy department is normally 4 treatments, each of approximately 1 hour, over a 4 week period. This programme is given as a group treatment where you will be with up to 9 other people (10 in total) who are also suffering from low back pain. The programme is run by two experienced physiotherapists. The group is a specialised programme and involves education and exercises based on current research evidence. In addition to attending the low back rehabilitation class you will be requested to continue with the exercises at home. This is to maximize the benefit of the rehabilitation programme. We carefully select patients to participate in our group programme and certain people cannot participate, for example, if you are pregnant, or if you have had surgery to your lower limbs in the past 12 weeks. People with low back pain who are ineligible to participate in the group receive alternative treatment.

If you are eligible for both the rehabilitation programme and for the research study and you choose to participate in the research study, you will be asked to wear either rocker sole sport shoes or flat sole sport shoes during the period of time that you are involved in the rehabilitation programme (i.e. 4 weeks) and for the following year. You will be requested to gradually increase the amount you wear the shoes from 1 hour per day, to two hours per day, to three hours per day, etc. You should aim to wear the shoes for at least two hours each day. This is important because we are trying to determine which shoe type might improve your low back pain condition, and we need you to wear the shoes for this period of time. We also ask that for the majority of the time that you are wearing the shoes, you are performing upright activities e.g. walking or standing. We will provide the shoes for you and you may keep the shoes after the study is complete. You will be required to document daily, the number of steps you have taken in the shoes. You will be provided with a diary to record your daily number of steps. The number of steps will be counted by a pedometer. You will also be asked to fill in an exercise diary on a daily basis.

Additional information

The low back exercise class time is set at the same time each week. This is to facilitate a regular period of time between each class and to ensure all the necessary equipment and teaching information is available at each class. If you agree to participate you will be required to attend the hospital once a week for a period of 4 weeks to attend the classes.

If you are eligible and choose to participate in this study you will be requested to complete a number of questionnaires about your low back pain. These questionnaires take approximately 20 minutes to fill in and involve placing a tick or mark next to an answer that you feel is the most appropriate. We will also measure how much movement there is in your lower back. These are routine tests performed by physiotherapists to assess the function of the lower back.

As this is a research study you will not be able to choose which group you will be in. This is to ensure that strict research standards are adhered to. If you agree to participate and after you have had your first series of tests with the chief investigator you will then meet with another researcher. It is only at this time you will know which group you will be in. The chief investigator will not be informed as to which group you have been allocated into. It will not be possible to change the group you are allocated to. You will then be fitted with either a pair of rocker sole sport shoes, or flat sole sport shoes. You will then be instructed how to walk effectively in the shoes, and how to use the pedometer, which will monitor the number of steps you take in the investigation period.

As this is a research investigation and we want to learn what is the most effective way to treat low back pain, we will ask your permission to measure your low back movements, amount of pain and to complete questionnaires on a further 3 occasions. This is to determine how the different treatments have affected you over time. The chief investigator will conduct all 3 re-assessment sessions. It is important that you do not let the chief investigator know which group you have been allocated to at any of these reassessment sessions.

We will request that you allow us to measure your range of movement, pain levels and to complete questionnaires at the following times:

(1) Before you start the lower back rehabilitation programme.
(2) At the end of the 4 week lower back rehabilitation programme.
(3) 6 months after joining the study
(4) 12 months after joining the study

That is four times in total (each time should take no more than 45 minutes).The measurements will be made in a private treatment area.

During the course of your treatment hospital transport will be provided for anyone requiring this service who meets the Trusts transport regulations. As we are asking you to return 6 months and 12 months after your treatment ceases we will reimburse your local travel costs if required.

The following table summarises the required involvement for this study for those agreeing to participate and who are eligible to participate.

	Consent form signed and first assessment (30 minutes) Following this, group allocation determined, shoes fitted, and pedometer use explained. (30mins)	Treatment period (4 weeks in total)	Post treatment follow-up Immediately following your last hospital treatment (This will not require an additional visit – just an additional 30 minutes to complete forms and undergo assessment following your last treatment).	6 Month Assess-ment	12 Month Assess-ment	TOTAL NUMBER OF VISITS TO HOSPITAL
Group 1: **Low back rehabilitation group and rocker sole sport shoes**	Yes	1 low back rehabilitation group per week of one hour for 4 weeks That is 1 hospital visit a week for 4 weeks.	Yes	Yes	Yes	8
Group 2: **Low back rehabilitation group and flat sole sport shoes**	Yes	1 lower back rehabilitation groups per week of one hour for 4 weeks. That is 1 hospital visit a week for 4 weeks.	Yes	Yes	Yes	8

Please note: If you already know that you will not be able to attend the programme once a week for four weeks, or that you may be moving abroad during the next year, we would request that you do not offer to participate. The reason for this is that all scientific investigations require that a certain number of people are followed for the entire time of the study. If there are not enough people at the end of the time period then the results of the study may not be of any meaning.

However, please remember that you are free not to participate and you are free to leave the study for whatever reason you choose at any stage. Your decision to leave the study will not affect the quality of care you receive.

It is important for you to know that there will be no difference in the waiting times for the lower back rehabilitation group for those agreeing to participate in this study and those not wishing to participate.

9. What do I have to do?

The first thing you need to do is decide if you would like to participate or not. This is entirely your decision and deciding not to participate will not affect the quality of your care. If you do decide to participate you will need to follow the procedure outlined in section 5.

10. What is the procedure that is being tested?

We are trying to determine if the addition of wearing a rocker sole sport shoes or flat sole sport shoes in addition to a specialised low back rehabilitation exercise group further helps to reduce pain and improve function.

We will be investigating this in a randomised clinical trial. This means that people participating in this trial will be randomly allocated into one of two groups; Group 1 (exercise and rocker sole sport shoes), and Group 2 (exercise and flat sole sport shoes). It is desirable that the two groups in this study should be as similar as possible with regards to characteristics that might influence the response to treatment. Randomisation is used to ensure that equal numbers of participants with a characteristic thought to affect the response to a particular intervention will be allocated to each of the two groups. To ensure the scientific integrity of this investigation a computer programme will determine your group allocation. You will not be able to choose the group you are allocated to. You will have a 1 in 2 chance of being placed in the exercise and rocker sole shoe group (Group 1), and a 1 in 2 chance of being placed in the exercise and flat sole shoe group (Group 2).

8. What are the side effects of taking part?

Some participants may find the physical tests (range of movement) for the lumbar spine produces some pain. In most cases this will be similar to the pain experienced in their back. The tests are used clinically to help determine which structure or structures are involved in their symptoms and are an essential part of the assessment procedure. We also perform these tests to see if you are improving as a result of the treatment you have received.

A subject walking in their new shoes may initially be aware of increased low back pain. Subjects walking in these shoes may attain a slightly different posture than normal. This can lead to an increased activation of the lower back muscles. When muscles start to work harder they can be painful. This should normally resolve within a few days. Additionally, a burning sensation may be experienced by certain individuals whilst wearing new shoes. This is due to increased blood flow to the small muscles in the foot. This should settle after a few weeks. Sensations such as pins and needles, sweaty feet and numbness may occur initially and will subside after wearing their shoes for a few days.

Participation in the exercise classes may also lead to an initial increase in discomfort. This is a well recognised phenomenon in any individual undertaking a new exercise programme and is known as delayed onset muscle soreness. It normally settles after a few days. If during the study your back pain symptoms worsen and do not settle after a few days, or you become aware of new symptoms, you are advised to contact the Chief Investigator, or your GP.

As with any new footwear, participants may develop blisters as a result of wearing either shoe type.

You may discuss any concerns you have with the clinical investigator, Siân MacRae, on 07504 294858.

9. What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages or risks for those taking part in this study. The examination procedures and treatment procedures are ones used daily in physiotherapy clinics.

10. What are the possible benefits of taking part?

We do not currently know the most effective treatments for low back pain and we hope that this research will help us understand the best way to treat this problem. However, as with all research, this cannot be guaranteed.

All participants will be at liberty to keep their shoes at the end of the study if they wish to do so. A pair of the more advantageous shoes, if found, will be given to all subjects at the end of the study.

11. What if something goes wrong?

We do not anticipate that anything will go wrong in this study as we are not trying any new procedure, we are simply investigating, in a scientific manner, the benefit of treatments currently received by people with low back pain.

However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms are available to you.

12. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

If you do participate your GP (and Consultant, if appropriate) will be sent a letter notifying them of your participation in this study (if you give your permission for this letter to be sent).

13. What will happen to the results of the research study?

We hope to use the information we obtain from this study to inform other health professionals about our results. We therefore ask your permission to publish the data we obtain. However, we guarantee to keep your name and identity confidential and this will not be made available to anyone at any stage. The results will probably be published about one year after the end of the study and if you are interested in finding out about our results, we would be happy to send you a one page summary of our findings.

14. Who is organising and funding the research?

This research is being organised by the Department of Physiotherapy at the Chelsea and Westminster Health Care NHS Foundation Trust. It has been funded by a research grant from MBT Physiological Footwear.

15. Who has reviewed this study?

This study has been reviewed by external experts. In addition it has been reviewed by the Hospitals Research and Development Committee and the Riverside Research Ethics Committees.

16. Contact for further information

If you would like any further information about this study, please feel free to contact Siân MacRae, Senior Physiotherapist, on telephone number 07504 294 858.

Additionally, if you are a patient and decide to participate in this research we will also ask you if you would like us to send a letter to your GP or consultant, informing them that you are participating in this study. We will also go through a series of screening questions to ensure that for ethical and healthcare reasons it is appropriate for you to participate in this study

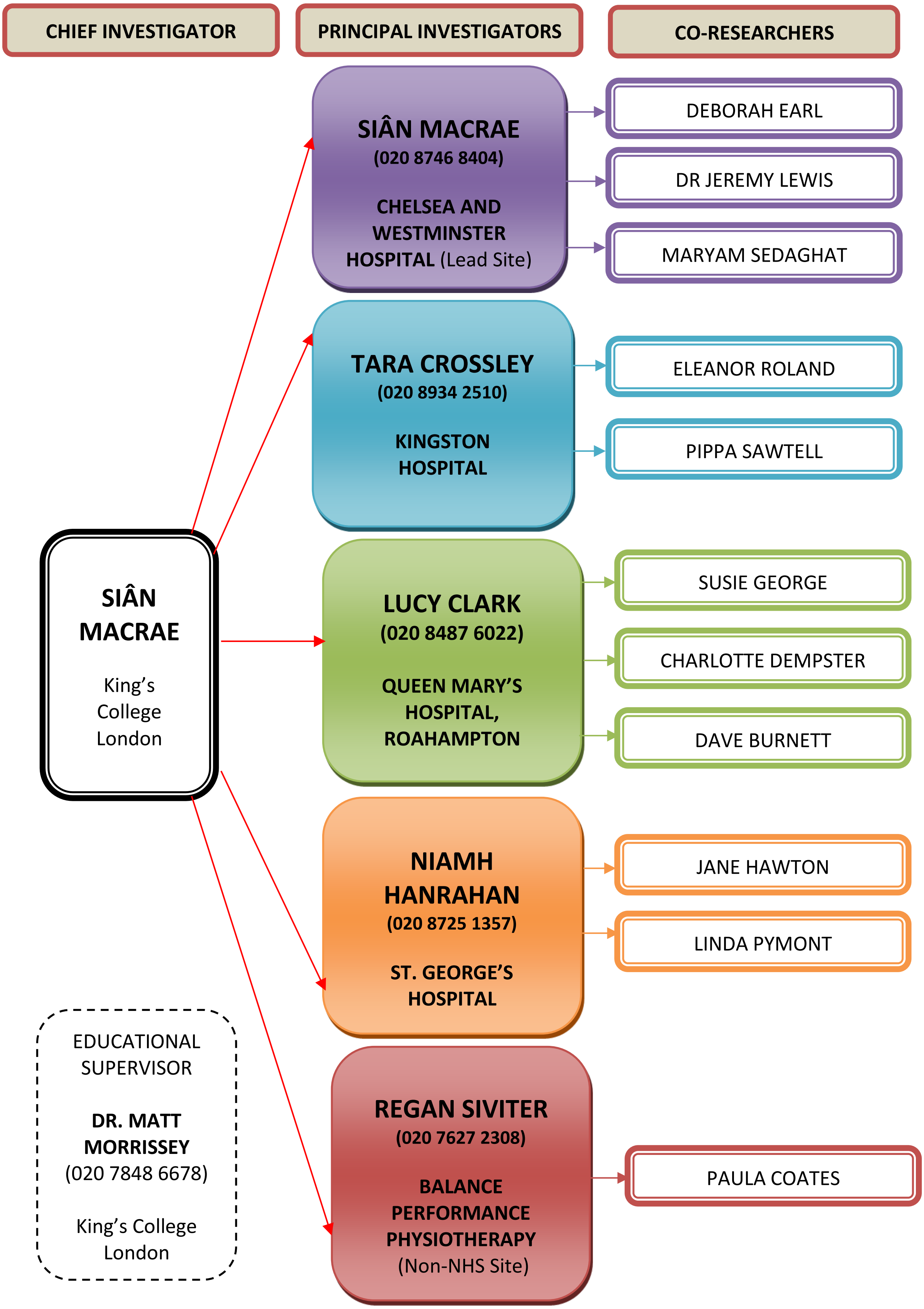
17. After you have read this information sheet

If you think you would like to participate in this study please take time to think about your involvement. You might find speaking to family and friends and other healthcare professionals helpful. If you do decide to participate we will ask you to fill in and sign a Research Consent Form, in front of someone who will witness the signature.

If you agree to participate you will be given a copy of this information sheet and a copy of the consent form you signed. If you are a patient and do not wish to participate then your physiotherapist will organise a course of treatment for you.

Thank you for taking the time to read this information sheet.

11.21 Principle investigators and co-researchers at research sites



11.22 Standing and walking instructions for study shoes

ROCKER SOLE SHOE (wording as recommended by shoe manufacturer)

Walking Technique:

“Begin by walking naturally on a flat surface.”

Cues:

- (Good speed): “Walk at a brisk pace.”
- (Short steps): “Shorten the stride length.”
- (Good posture) “Walk with good posture…”
    - (Draw up crown of head): “Lengthen your spine by drawing the crown of your head up.)
    - (Proper gaze): “Look straight ahead.”
    - (Tummy in): “Pull your lower abdominal muscles in to help activate your core stability.”
    - (Shoulders back): “Bring your shoulders back and in line with your ears and hips.”
- (Swing arms with proper trunk movement): “Gently swing your arms and move your torso as you walk.”
- (Roll through): “Make sure you roll through the feet with every step.”
    - (Demonstrate proper roll through)
    - (Demonstrate where the heel sensor should hit): “Your foot should contact at the heel. As your foot rolls through from heels to toes, roll through the centre of the foot. When your foot pushes off, the weight in your toes should be evenly distributed so that the pressure is from the middle rather than to one side.”

Standing Exercise:

- (Foot position): "Stand with your feet parallel and shoulder width apart."
- (Rock through the feet): "Roll forwards and backwards through the feet and ankles…
- (Find the Pivot Area): "…feeling the pivot area just in front of the heels."
- (Heels and toes off floor): "Come to rest on the Pivot area. You should feel that your heels and toes are slightly off the floor."
- (Posture): "Draw up your posture, lengthening your spine, gently drawing your shoulders back and softening your knees."

Correction of Wrong Technique: "When wearing your shoes, certain mistakes can occur. Be aware that you are walking properly in your shoes to gain the maximum benefit."

- (Watching feet): "Do not watch your feet or the floor – look straight ahead when wearing your shoes."
- (Slouched posture): "Walk and stand with good posture at all times."
- (Poor core control): "Remember to engage your core muscles."
- (Stiff arms): "Walk with a relaxed, natural gait letting your arms swing gently and your torso move."
- (Over-pronation): "Do not let your feet roll in when you stand or walk."
- (Flat foot-strike): "Roll through the foot to get the full benefit of the shoes."
- (Pain): "Walking should feel comfortable and natural. If you have pain, stop and check your technique or consult with your physiotherapist."

Fitting: "Always make sure your shoes are snug on the instep, tight on the heel and comfortable on the toes."

- **Should not**: "Your shoes should not slip at all, squeeze or rub the toes, press on the tips of your toes, rub against the ankle bones or cause you any pain.

- **General medical precautions**: "When you first start wearing your shoes you may experience certain short-term effects. These include tingling in the feet and toes and general aches in the muscles. These effects normally stop within one to two weeks of wearing them."
- **Build up the amount of time you wear your shoes**: Start wearing the shoes for 15 to 30 minutes per day building up daily over the first week to two hours**.** Progress only as your comfort allows, to wearing a minimum of two hours per day.
- **Comfort:** If you encounter any problems with wearing your shoes, please contact your physiotherapist to discuss.

FLAT SOLE SHOE (wording altered from rocker sole shoe instructions above to apply to the flat sole shoe)

Walking Technique:

"Begin by walking naturally on a flat surface."

Cues:

- (Good speed): "Walk at a normal pace."
- (Normal stride): "Walk with your normal stride length."
- (Good posture) "Walk with good posture…"
    - (Draw up crown of head): "Lengthen your spine by drawing the crown of your head up.)
    - (Proper gaze): "Look straight ahead."
    - (Tummy in): "Pull your lower abdominal muscles in to help activate your core stability."
    - (Shoulders back): "Bring your shoulders back and in line with your ears and hips."
- (Swing arms with proper trunk movement): "Gently swing your arms and move your torso as you walk."
- (Roll through): "Make sure you roll through the feet with every step."
    - (Demonstrate proper roll through)
    - (Demonstrate where the heel should hit): "Your foot should contact at the heel. As your foot rolls through from heels to toes, roll through the centre of the foot. When your foot leaves the floor, push off through your big toe"

Standing Exercise:

- (Foot position): "Stand with your feet parallel and shoulder width apart."
- (Heels and toes on floor): "You should feel that your weight is evenly distributed over both feet."
- (Posture): "Draw up your posture, lengthening your spine, gently drawing your shoulders back and softening your knees."

Correction of Wrong Technique: "When wearing your shoes, certain mistakes can occur. Be aware that you are walking properly in your shoes to gain the maximum benefit."

- (Watching feet): "Do not watch your feet or the floor – look straight ahead when wearing your shoes."
- (Slouched posture): "Walk and stand with good posture at all times."
- (Poor core control): "Remember to engage your core muscles."
- (Stiff arms): "Walk with a relaxed, natural gait letting your arms swing gently and your torso move."
- (Over pronation): "Do not let your feet roll in when you stand or walk."
- (Flat foot-strike): "Roll through the foot to get the full benefit of the shoes."
- (Pain): "Walking should feel comfortable and natural. If you have pain, stop and check your technique or consult with your physiotherapist."

Fitting: "Always make sure your shoes are snug on the instep, tight on the heel and comfortable on the toes."

- **Should not**: "Your shoes should not slip at all, squeeze or rub the toes, press on the tips of your toes, rub against the ankle bones or cause you any pain.
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- **Comfort:**   If you encounter any problems with wearing your shoes, please contact your physiotherapist to discuss.

11.23 Participant assessment sheet

Assessment No: ……… SUBJECT No: ……………

MALE/FEMALE Weight: ……………………..Kg Height/cm: …………..

D.O.B: ……………………… BMI:…………………………

Duration of symptoms: ………………………… Constant/Intermittent: …………………

Previous conservative treatment:

………

Present analgesic requirement:

………

Main functional problem: ………………………………………………………… Score: ……… / 10

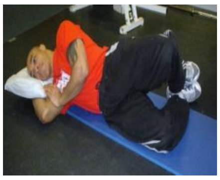
	Reading 1	Reading 2	Reading 3	Average	Pain NRS /10
Lumbar Flexion /cms					
Lumbar Extension /cms					
Lumbar RSF /cms					
Lumbar LSF /cms					
Right SLR /degs					
Left SLR /degs					
Thoracic kyphosis angle/degs					
Waist circumference/cms					

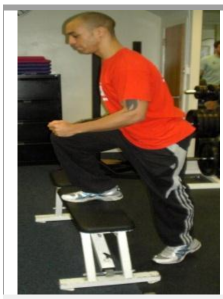
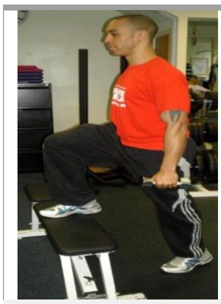
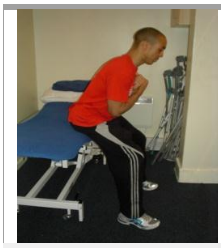
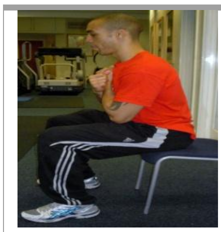
Name of Assessor: ………………………………… Signature of Assessor: ………………………..

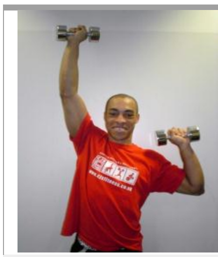
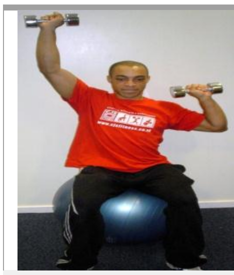
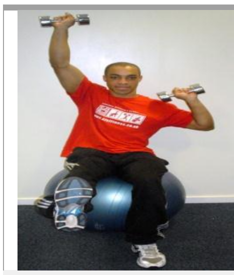
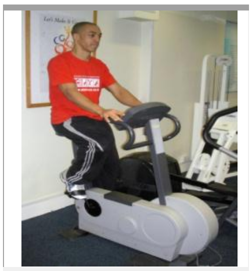
Date of Assessment: ……………………………….

11.24 Low back pain group exercises

Exercise	Level	Exercise description	Picture
REVERSE CURL-UP	1: Beginner	Lie on back with knees bent, feet flat on floor, and hands under small of back. Slowly raise one foot a short distance from the floor, bringing knee towards you. Then slowly lower foot back to floor. Keep back still.	
	2: Intermediate	As beginner. Raise foot from floor bringing knee closer to chest, slowly lower. Keep breathing	
	3: Advanced	As intermediate. Maintain position for 5 seconds, pressing opposite hand into raised knee. Keep breathing.	
BIRD DOG/ SUPERMAN	1: Beginner	On hands and knees. Raise one arm or leg at a time to the horizontal. Keep back still – do not let you lower back arch or dip.	
	2: Intermediate	As beginner. Now raise opposite arm and leg together, do not raise past horizontal. Do not let back arch or dip. Hold for 5-10 seconds.	
	3: Advanced	As intermediate. Now sweep opposite hand and knee together and repeat – don't let them rest on the floor in between repetitions.	

CLAM	1: Beginner	Lie on your side. Keeping your back straight, bend knees to 90 degrees keeping thighs in line with your body. Raise your top knee from your lower knee by squeezing bottom muscles together. Slowly lower.	
	2: Intermediate	As beginner. Straighten your top knee. Raise and lower top leg, keeping foot facing forwards.	
	3: Advanced	As intermediate. Raise top leg and pulse leg up and down. Remember to draw in lower abdominal muscles.	
BRIDGING	1: Beginner	Lye on your back, arms by sides, and knees bent. Squeeze buttocks, raise and lower pelvis. Keep hips level.	
	2: Intermediate	As beginner. Now place arms across your chest. Squeeze buttocks, raise and lower pelvis. Keep hips level.	
	3: Advanced	As beginner. Straighten one leg. Squeeze buttocks, raise pelvis up and down. Keep hips level.	
PRESS-UPS	1: Beginner	Press up leaning against the wall	

	2: Intermediate	On hands and knees, bend elbows, lowering head to the floor. Keep low back still.	
	3: Advanced	Move knees further away from hands, progressing to full press-ups. Keep low back still.	
STEP-UPS	1: Beginner	Step up and down on low step	
	2: Intermediate	Step up and down on high step	
	3: Advanced	Raise arms above head as step up/ or add arm weights	
SIT TO STAND	1: Beginner	Sit to stand from raised plinth	
	2: Intermediate	Sit to stand from low plinth/chair, cross hands over chest.	

	3: Advanced	Sit to stand on one leg/or hold arm weights as stand up	
SHOULDER PRESS	1: Beginner	Stand with weight in each hand at shoulder height, raise each arm alternately.	
	2: Intermediate	As beginner, but sitting on gym ball. Keep back still. Don't slump.	
	3: Advanced	Sit on ball and raise one leg whilst raising weights.	
WOBBLE-BOARD	1: Beginner	Stand as still as possible on surface (2 legs), keeping all edges off the floor	
	2: Intermediate	Standing on one leg – keep as still as possible, keeping all edges off the floor.	
	3: Advanced	Stand on wobble-board, throw and catch ball.	
EXERCISE BIKE	1: Beginner	Pedal slowly	
	2: Intermediate	Increase speed	
	3: Advanced	Increase resistance	

11.25 Low back pain group education sessions

<u>1 : EXERCISE</u>

WHY DO WE EXERCISE?

1. Regain movement/function
2. Maintain or gain general physical fitness i.e. loose weight.
3. Maintain or improve movement/function i.e. training for specific reason/event.
4. Enjoyment.
5. Social interaction.
6. Sense of achievement.

THE NORMAL EFFECTS OF EXERCISE ARE: -

1. Increased heart rate.
2. Increased breathing rate.
3. Increase in temperature.
4. Sweat.
5. Muscle Fatigue.

Exercise also stimulates the body to release endorphins, which are the body's natural painkillers, thereby reducing pain and increasing your pain thresholds (i.e. the level at which you feel the pain).

WHY WARM UP?

1. **Prepare the body** for exercise especially heart and lungs.
2. **Increase circulation** to muscles.
3. **Reduce risk of injury** to the muscles during the exercises by stretching.
   Stretching should be performed once the muscles have been warmed up to prevent injury.

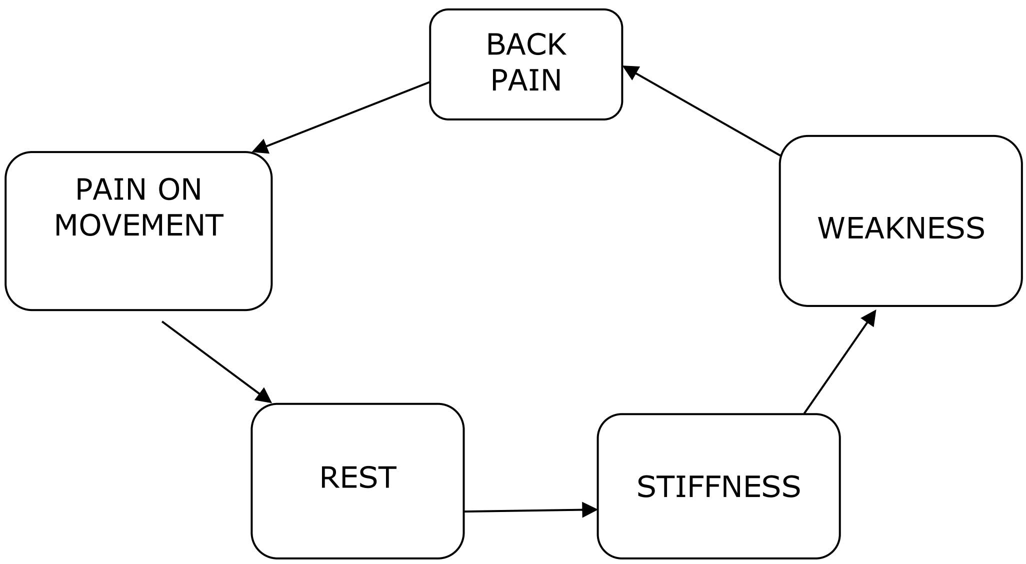
POINTS TO REMEMBER WHEN STRETCHING

1. **Do not bounce**, but push gently into the stretch.
2. **Hold each stretch** for at least 10 seconds. (increase to 30 seconds for soft tissues to really lengthen)

3. You should **feel no pain**; the muscle tension should "give" the longer you hold the stretch.
4. **Stretch** each side **equally.**

EXERCISE PACING

Pain over a period of time reduces activity levels and creates a 'fear' of exercise. To avoid an increase in your symptoms it is important to do appropriate exercise, as too much of the wrong exercise can increase pain and reinforce the idea that movement is causing harm. It is likely that you are experiencing "deconditioning" i.e. that there is reduced strength and endurance due to the lack of an exercise routine.



Appropriate exercise will help to break this cycle.

1. Set an **achievable number of exercises** or time yourself.

2. Regulate your daily exercises to **balance exercise** and **rest** to avoid exacerbating your pain.

3. Set aside a **regular time** to do your exercises.

4. Make **achievable goals** for the following week, to gradually work towards your final aim. Progress the number of repetitions, duration of exercise, weights etc.

5. Pick an **exercise you <u>enjoy</u>** and are likely to continue.

<u>2: DEALING WITH FLARE UPS</u>

- ***What is a flare up?***
  A flare up is a temporary increase in pain or return of symptoms.

- ***How long do they last?***
  This varies but can be anything from a few hours to a couple of weeks.

- ***What symptoms are normal to experience?***
  The symptoms are different for everyone but can include pain, swelling, stiffness, spasm, weakness, tingling, burning, aching, or locking.

- ***Why do I get flare ups?***
  It is usually because you have done **too** much or **too** little. Most people can think back to a change in activity, or a situation, where they did too much or something new. eg gardening for a day, or it may just be a combination of things that could have caused a flare up. Colds, flu, stress and anxiety and lack of exercise can all lead to flare ups.

- ***Have I damaged myself?***
  No! If you ran a marathon without training for it, you would expect to be very sore for a few days afterwards. This is not damage but normal training pain as your body has worked outside of its normal tolerance. Athletes gradually building up their marathon training week by week for weeks/ months to help minimise pain. This is called pacing – a gradual return to activity so the body can adjust and strengthen in preparation. Remember even though you used to be able to do certain activities you need to build your tolerance up before returning to such activities.

Suggested strategies for a flare-up plan

Don't panic!

- Any added stress or tension will build up in the muscles; sore joints will feel worse if tense muscles are surrounding them.
- Try the relaxation and breathing exercises you have learnt to allow the muscles to let go.
- It has happened before and you have got through it!

Challenge unhelpful thoughts

- A flare up can be a worrying time and it is important not to let negative thoughts hinder your progress.
- Remember, pain does not necessarily mean damage and hurt does not always mean harm.
- Setbacks are a common part of the recovery process and will give you valuable information about your body and its tolerance levels.
- Don't be discouraged! Remember your flare up will pass.

Pacing /plan your day

- If possible, rearrange activities to allow you to pace more effectively. This is often the hardest bit!
- Try and keep at least one pleasure activity.

Use heat or ice

- Muscle spasm is often the main source of pain during a flare up; it is the body's way of protecting itself although sometimes it can be an over-protective.
- Heat is often helpful to release painful muscle spasms and allow the muscles to relax.

- Cold packs are considered better for initial acute pain and the cold will help settle any temporary inflammation that has occurred.
- Long term inflammation is not helpful so it is important to help settle it down.

Stretch

- Tight muscles are a common source of unnecessary pain. It’s important to gently stretch these out as soon as possible.
- Gentle controlled stretching can help release any muscle spasm. It helps if your muscles are warm before you stretch them. After a bath or gentle activity is good.

Gradually Restore Full Movement

- To avoid movement as a result of pain is often the worst thing you can do.
- Give the body the right message that movement is good by continuing your exercises.
- Resist the temptation to avoid anything that may bring on the pain.
- By all means adjust how far you move into the exercise - try and stick to the numbers even if you are not moving as far.
- As a last resort if you are not managing – reduce the number of exercises to half but immediately plan a gradual build up back to your normal amount over the next 5 days.

It takes patience and confidence to keep going, without overdoing it. It is important to find the right balance between too much and too little.

3: PAIN

Acute and Chronic Pain

- Acute Pain is the pain we feel immediately after injuring ourselves and while the injury is healing, i.e. touching a hot object.
- Chronic pain is pain that continues even though healing has occurred, or pain that has been present for more than 3 months.

How We Feel Pain – Acute pain

- We have sensors (receptors) in our skin, ligaments, muscles, joints and other structures in our body.
- These all have different functions – they are activated when there is heat, pressure, stretch, and also strong input.
- The information from the tissues is sent along nerves, via the spinal cord, to the brain which *interprets* the message.
- When the nerve itself is irritated it can give symptoms such as pins and needles, numbness, burning or shooting sensations.
- Acute pain is helpful – it makes us take things easy to allow healing to occur.

How We Feel Pain – Chronic pain

- With chronic pain the link between pain and damage is complicated.
- It is not unusual to find no direct link between your pain and the original damage which may have long healed.
- Chemical changes happen in the brain and spinal cord to re-route signals to pain centres in the brain.
- Normal sensation – movement, touch, pressure, stretch, hot, cold can therefore all be felt as pain.
- Sometimes the pain system can be activated without even any physical stimulus – by changes in the weather, by mood and thoughts or even no stimulus at all…
- It is as if the nerve system can make its own pain!

What makes your pain worse?

- If you are able to recognise all the different factors that can contribute to your pain experience, you can learn techniques to deal with them better. For example:

    - Physical demands on your body (over exertion)
    - Not doing enough physical activity (under exertion)
    - Stress
    - Anger
    - Fatigue
    - Anxiety
    - Low mood

Turning the pain up and down

- Have you ever had an injury and not felt it at the time?
- The nervous system is very good at filtering information.
- In extreme situations, such as danger, your brain and spinal cord have to filter out what it doesn't consider as important at the time - it can filter out pain signals.
- It releases natural pain killing chemicals into the blood stream and these can damp down and reduce the pain signals. These include Endorphin, Encephalin and Serotonin.
- The natural pain killing system doesn't just occur in an emergency. In normal life, when you are not stressed and are in control of your pain, the brain also releases these pain killing chemicals into the bloodstream.
- However the nervous system may see pain as a threat and can trigger a state of alertness, which is a type of stress response.
- In this state of alertness it will look out for any pain signals and odd sensations throughout the body. It can choose to highlight this information as pain information, instead of filtering it out.
- When this occurs the brain stops releasing the natural pain killing chemicals and releases other hormones, such as adrenalin, into the bloodstream.
- In the long term, this stress response can make your pain worse. It can cause changes to muscle tension, blood pressure, breathing rate . . .

- Clinical research has clearly shown that the more you are unaware of why you have pain, the less confident you are to deal with it; the more worried you are about your pain, the more you will activate your brain's pain centres and the more you will switch off your brain's painkilling system.
- Conversely, the more confident you are to deal with your pain, and the more you are in control of it, the more you will activate your brain's painkilling system.

Techniques to help manage your pain

- We can produce more of our own pain killers two ways: exercise and relaxation
- Clinical research has clearly shown that the ability to relax deeply is vital to our emotional well-being and physical health.
- As the pace of modern life continues to accelerate, relaxation may be used as a simple way of reducing tension, stress and anxiety.
- It can also be an extremely effective tool in the management of chronic pain.
- You can get similar benefits from doing activities you enjoy:
    - Going for a walk in the fresh air
    - Exercising
    - Singing
    - Going out and seeing friends
    - Having hobbies and interests

Pain and Sleep

- You will often experience greater levels of stress and pain when you are tired so it is important to get restful sleep.
- Bedtime is a time with fewer distractions so worrying negative thoughts have the opportunity to come through.
- Here are some suggestion to aid more peaceful sleep:

    - Exercise, particularly in the afternoons, can enhance sleep.
    - Use your bed and bedroom for sleep only.
    - Before going to bed, write down any problems of the day or unfinished tasks and note the next action to be taken (unfinished business like this can disturb sleep).
    - Perform a relaxation session before going to sleep.

- If you wake up in the night worrying, write it down to deal with the next day.
- If you are lying awake for say 20 mintues, don't clock watch – get up and do something relaxing.
- If you are not tired when you go to bed, get up earlier in the mornings.
- Quality of sleep before midnight is better than that late into the morning.

Pain and Posture

- Postures are partly developed genetically but are also altered by the environment and our lifestyles.
- Maintaining ANY position or activity for too long builds up stresses on our joints and soft tissues (ligaments, muscles, nerves) which can cause pain.
- Your body needs to have a healthy balance of strength and flexibility.
- Joints and the surrounding soft tissues need to move and stretch regularly to maintain strength and flexibility otherwise they get short and tight, or long and weak.
- Short muscles can become overactive and long muscles don't get 'switched on' as easily; the surrounding area becomes less well supported and is vulnerable to pain.
- Many people who maintain one position for hours at a time sitting at a computer for example can develop back, neck and shoulder pain.
- You should change position or activity every 20-30 minutes.

4: RELAXATION

WHY DO WE NEED TO RELAX?

- To decrease levels of stress/tension in the body
- To decrease pain
- To decrease fatigue
- To improve sleep patterns

PROLONGED TENSION CAUSES:

- Aches, discomfort, tiredness
- Stiff movement
- Worry, frustration, irritability and stress

LEARNING TO RELAX CAN ALSO HELP:

- Reduce blood pressure
- Reduce heart rate

HOW TO LEARN TO RELAX:

- Allow yourself time each day to learn how to relax
- Give yourself quiet time to relax
- Using music or a relaxation tape may help
- Find a comfortable position and close your eyes
    - In this position practise deep breathing. Concentrate on feeling your ribs rise and fall for a few breaths.
    - Then tense each part of your body in turn for a count of 10. Do this as you breathe in, and feel the tension. Then breathe out and let the muscles relax.
        - Toes - curl toes towards the floor
        - Calves – point toes away from you
        - Buttocks – clench your buttocks
        - Stomach – squeeze stomach muscles
        - Shoulders – shrug shoulders to ears
        - Neck – press your chin in your chest
        - Face – screw up your face
        - Hands – make a fist

RELAXATION SESSION.

Sit back comfortably in a chair, or lie down, so that your body is well supported. Close your eyes to shut out distractions. Listen to the sounds around you and identify them. If you identify the sounds, they will not intrude.

Now be very aware of the support for your body. Feel the contact with that support. Feel that it is safe enough for your body to let go. Notice your feet, be aware of their position, where they are pointing and where they are touching the ground. Scrunch up your toes, hold it briefly and let go. Feel your calves and back of your knees. Tighten your knee muscles then let the tension ease out of them. They should feel relaxed and light. Feel the contact between your hips and thighs to the contact surface. Now gently tighten those muscles and let that tension drop away. Feel the position of your back on the supporting surface, you can feel the curves and pressure through your back and feel that it is safe to let it go.

Next, feel your breathing. Feel that your rib cage is relaxed and able to gently rise and fall. Feel each breath go into the base of your lungs and gently pass out through your mouth.

Now, feel the position of your arms. Where are your hands? Feel each finger tip. What is the texture under your hands? Squeeze your fingers together and let go. Be aware of your elbows and tighten gently your arm muscles for a few seconds and let go. When the elbows feel supported, feel how your shoulders let go. Pull the points of your shoulders up to your ears. Feel the activity in the muscle and gradually let the muscle go so that your shoulders sink down towards your waist.

Now, feel the support for your head. Let the pillow or contact surface take the weight of your head. Tighten your neck muscles by ‘nodding yes’ and then let all tension subside. Lastly, be aware of your face. Let your expressions drop to a neutral resting position. Scrunch up your forehead and scalp. Hold this briefly and let the tension fade away. Your eyes should now be effortlessly held shut. Scrunch up your nose and mouth – again hold the tension briefly then feel able to let the muscle activity level drop down to nothing.

Notice your jaw – let it sag a little and allow your teeth to separate a bit. When your jaw is loose, your cheeks will be soft. Now lie there for a few moments, enjoying the feeling of resting quietly.

11.26 Biomechanics study participant information sheet for studies in Chapter 7 and 8

PARTICIPANT INFORMATION SHEET

V 2. Date 09.03.2010

1. Study title

Low back pain: Can shoe type reduce the pain and recurrence rate? A biomechanical assessment.

REC No: 10/H0724/7

2. Invitation paragraph

You are being invited to take part in a research study aiming to investigate the potential beneficial mechanisms that may be involved in the short and longer term use of different footwear types in the treatment of low back pain. Before you decide to participate it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your GP, Consultant, or the Chief Investigator of the study, if you wish. Please ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part. There will be no difference in waiting times for your treatment if you decide that you do not wish to participate in this research study. Please let us know if you are currently participating or have recently participated in another research project. If you have, it may not be appropriate for you to consider participating in this study.

3. What is the purpose of the study?

What we are aiming to achieve in this study is to determine if the addition of wearing either a flat sole sport shoe or a rocker sole sport shoe to traditional physiotherapy exercises and rehabilitation improves the outcome for patients with low back pain. Research suggests that shoe type may be influential in reducing the stresses that pass up through the spine, improving muscle activation around the spine, and in doing so may further help to facilitate an improvement in outcome for patients with low back pain. There is, however very little guidance as to the best type of footwear to achieve these effects. This project aims to provide further evidence regarding the best practice in treatment of chronic low back pain. This biomechanical study will be conducted to explore the potential effects short term (4 weeks) and longer term (6 months) use of rocker sole shoes and flat sole shoes may have on people with low back pain over time.

4. Why have I been chosen?

If you are eligible to participate in the research study investigating footwear and low back pain (REC: 09/H0706/4) you may also be asked if you would be happy to take part in this additional biomechanical study. It is up to you to decide whether or not to take part. You may choose to be involved in this biomechanical study in addition to the back pain and footwear study, or to just participate in the back pain and footwear study. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form before the study starts. If you decide to take part you are still free to withdraw at any time and without giving a reason. Refusal to participate or subsequent withdrawal will not affect the standard of care you receive.

5. What will happen to me if I take part?

The aims of the biomechanical study are to assess whether the study shoes have an effect on your posture, balance, and the way you move. If you chose to participate in this additional study you will be required to attend the gait laboratory at Guy's Hospital on three occasions:

(1) Before you start the lower back rehabilitation programme.
(2) At the end of the 4 week lower back rehabilitation programme.
(3) 6 months after joining the study

We will ask you not to wear the study shoes you receive at your referring physiotherapy department until you have undergone the initial assessment in the gait laboratory. These two appointments will be approximately one week apart.

The assessment in the gait analysis laboratory will consist of the following:

- You will be asked to stand on a force plate (a measuring instrument on the floor that measures forces generated by you whilst standing on or moving across it) for three 40 second trials under different balance situations, for example, standing on an unstable surface such as a piece of foam, or standing with your eyes-closed. For the eyes-closed assessments we will ask you to wear a blindfold. Small markers will be placed at different points on you legs and trunk, which will enable us to analyse how you are moving during the tasks.
- You will also be asked to walk in the laboratory, whilst still wearing the markers on your skin. This will enable us to assess the movements that occur at your joints, and the forces that occur whilst you are walking both in your study shoes and barefoot.
- Certain measurements of your lower limbs (such as the width of your ankles, and the distance between your ankle and your knee) will be recorded by the chief investigator during your initial visit using a tape measure or callipers. These measurements will be used by the chief investigator in the analysis of the data recorded during your visits.
- You will also be asked to complete a questionnaire regarding how your low back pain may affect your day to day activities. This should take 2-3 minutes to complete.

The markers will be placed on your legs and pelvis trunk with double sided sticky tape, and removed at the end of the assessment. The assessment in the laboratory will take approximately 1 hour. As we are asking you to travel to Guy's Hospital on 4 occasions for assessment reasonable travel expenses to and from home to Guy's Hospital will be reimbursed on request.

The chief investigator, Sian MacRae, will conduct all 3 assessment sessions. It is important that you do not let the chief investigator know which group you have been allocated to at any of these reassessment sessions.

The following table summarises the required involvement for this study for those agreeing to participate and who are eligible to participate.

	Baseline Assessment Consent form signed, body measurements, standing balance and walkingassessment **1 hour**	**4 week Assessment** Standing balance and walkingassessmen t **1 hour**	**6 Month Assessment** Standing balance and walkingassessm ent **1 hour**	**TOTAL NUMBER OF VISITS TO THE GAIT LABORATORY GUY'S HOSPITAL**
Participants in Footwear and Low Back Pain Research Study (REC 09/H0706/4 and 10/H0724/7)	Yes	Yes	Yes	3

Please note: If you already know that you will not be able to attend the three sessions or that you may be moving abroad during the next 6 months, we would request that you do not offer to participate. The reason for this is that all scientific investigations require that a certain number of people are followed for the entire time of the study. If there are not enough people at the end of the time period then the results of the study may not be of any meaning.

However, please remember that you are free not to participate and you are free to leave the study for whatever reason you choose at any stage. Your decision to leave the study will not affect the quality of care you receive.

6. What do I have to do?

The first thing you need to do is decide if you would like to participate or not. This is entirely your decision and deciding not to participate will not affect the quality of your care. If you do decide to participate you will need to follow the procedure outlined in section 5.

7. What is the procedure that is being tested?

We are trying to determine if the addition of wearing a rocker sole sport shoes or flat sole sport shoes in addition to a specialised low back rehabilitation exercise group effects the static and dynamic biomechanics of people with low back pain. We aim to further investigate whether any such changes correlate with an alteration in pain and function.

8. What are the side effects of taking part?

Following the removal of the body markers at the end of the biomechanical assessment you may be aware of a slight redness/itchiness of the area directly underlying where the marker had been placed. This is normal and should settle in approximately one hour.

9. What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages or risks for those taking part in this study. The examination procedures are ones used daily in gait laboratories.

10. What are the possible benefits of taking part?

We do not currently know the most effective treatments for low back pain and we hope that this research, investigating the potential biomechanical changes in people with low back pain wearing different designs of footwear, will help us understand the best way to treat this problem. However, as with all research, this cannot be guaranteed.

11. What if something goes wrong?

We do not anticipate that anything will go wrong in this study as we are not trying any new procedure, we are simply investigating, in a scientific manner, the potential effects footwear may have on the biomechanics of people with low back pain.

However, if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms are available to you.

12. Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it.

If you do participate your GP (and Consultant, if appropriate) will be sent a letter notifying them of your participation in this study (if you give your permission for this letter to be sent).

13. What will happen to the results of the research study?

We hope to use the information we obtain from this study to inform other health professionals about our results. We therefore ask your permission to publish the data we obtain. However, we guarantee to keep your name and identity confidential and this will not be made available to anyone at any stage. The results will probably be published about one year after the end of the study and if you are interested in finding out about our results, we would be happy to send you a one page summary of our findings.

14. Who is organising and funding the research?

This research is being organised by the Division of Applied Biomedical Research, Kings College London.

15. Who has reviewed this study?

This study has been reviewed by external experts. In addition it has been reviewed by the Hospitals Research and Development Committee and the Outer North London Research Ethics Committee.

16. Contact for further information

If you would like any further information about this study, please feel free to contact Siân MacRae, Senior Physiotherapist/Doctoral student, on telephone number 07504 294 858.

17. After you have read this information sheet

If you think you would like to participate in this study please take time to think about your involvement. You might find speaking to family and friends and other healthcare professionals helpful. If you do decide to participate we will ask you to fill in and sign a Research Consent Form, in front of someone who will witness the signature.

If you agree to participate you will be given a copy of this information sheet and a copy of the consent form you signed.

Thank you for taking the time to read this information sheet.

11.27 Gait laboratory calibration protocols

C1 Protocol for the Routine Calibration of Forceplates & Analysis Space

Modified: Tanya Sale, Laura Wherity; Date: 06 August 2009

Approved: Adam Shortland. Date: 20/11/2009

Modified: Adam Shortland Date: 28-10-2010

To be performed at the beginning of each day containing a gait analysis. The power to the forceplates should be on permanently. If not, turn on power to forceplates 2 hours prior to calibration.

Force plate calibration

1. Use a shim to check for and remove any material that has got into the gaps around the forceplates.
2. With a trimmer of an appropriate size, adjust pots for each channel on each forceplate amplifier (AMTI) until the channel is balanced (green lights go out).
3. Check switches on Forceplate amplifiers – ensure that the filters are set to 1050 Hz and the gain is set to 2000.

Calibration of analysis space

1. Turn on laboratory PC.
2. Switch on the giganet box and open Nexus 1.4.116.
3. In the subjects section on the left hand side ensure that no subjects are checked. Make sure that the system setting is on Guy's Hospital 2. In the resources section on the left hand side highlight the MX cameras under Local vicon system, then in the properties section below, change the grayscale mode to all. Select camera view in the middle window, so that the view from all cameras can be seen in Live mode. Place the MX calibration wand on forceplate 2.
4. Zoom in to check that all the markers can be seen on the calibration wand correctly (grey and white pixels slightly overlapping the circle representing the marker) for each camera
5. Change the grayscale mode back to auto. Remove the calibration wand from the analysis space.
6. In the tools section on the right hand side click the "system preparation" button. Ensure "5 marker wand and L-frame" is selected in the wand and L-frame drop down menus.

7. Create MX camera masks by pressing the start button, waiting two seconds and pressing the stop button.
8. Under calibrate MX cameras click “show parameters” and check that the settings are: Full Calibration; MX cameras; 200; 1600 and the autostop is selected. Press “start” and wave the wand through the analysis space, letting each camera see the wand from different perspectives, until blue light on every camera stops flashing.
9. Under MX Camera Calibration feedback check that the wand count and image error boxes are green for all cameras and record the image error on the data collection sheet to 3 signficant figures. If the wand count and image error boxes are not green repeat step 7.
10. Place the calibration wand on forceplate 2 (central forceplate) with the handle pointing towards camera 7 (and the penguins). Locate the calibration wand at the corner of the forceplate, and adjust the screws on the wand until the spirit levels indicate level.
11. Change the middle window to 3D perspective. Under set volume origin click “start”, followed by “set origin”. The calibration wand should now be visible in the correct position on forceplate 2. If it is not repeat the calibration process.
12. Put the calibration wand away in the store room.

<u>Static Daily Weight Test Protocol:</u>

1. Make sure the force plate amplifier potentiometers (pots) have been zeroed (all green lights are off)
2. Reduce force threshold to zero (In Nexus live, in the System tab, select Force Plates and click to show the Advanced Properties in the Properties window below. Expand the Force Threshold field and move the main slider so all three devices are zero)
3. Start recording a trial named Weight Test with nothing on the FPs, then after c.1 second wheel the trolley with 30kg onto FP1, move to FP2, move to FP3, end trial
4. Run the ResetFPs pipeline function
5. View the Fz forces for each forceplate (In Nexus non-live, in the System tab, select Force Plates and expand to highlight all three Force/Fz fields (hold down control to select more than one field at once). Also ensure the tabs at the top of the main window are changed from 3D Perspective to Graph,and Trajectory Count to Components.
6. Move the time bar to locate a static portion of Fz for each force-plate and record the Fz value on the patient data-sheet for the trial and then in the three grey columns on the left. If outside the set tolerance the cells will turn green, if not, then red.

Note: The trolley is 6.1 kg + 30kg = 31.6kg = 354.14N. The tolerance is set on the right with the upper and lower limits automatically calculated.

<u>Daily Dynamic Pole Test</u>

1. Dynamic data for each force plate is to be collected in a single trial.
2. Start collecting dynamic data by placing the stick at the centre of each force plate in turn. At the corners, the stick should be positioned approximately 5 - 6cm from the edge of the plate. Start off by positioning the stick vertically and apply as much force

as possible (greater than 50N). Then, whilst pushing down on the stick, move the stick around the point of contact.

3. Be careful not to apply off-axis forces to the pole.
4. Apply reset forceplate offsets in software.
5. Inspect data in the workspace window to assess agreement between direction and origin of the force vector and the direction and position defined by the pole.
6. Record pass/fail on patient sheet.

Signed... Date:...............................

C2 Protocol for the routine static calibration check of the forceplates

Author: Tanya Sale, Adam Shortland

Date: 12th February 2010

- To be performed at 6 monthly intervals..
- Requires 2 people

1) Zero the forceplates on the forceplate pots.
2) Open 'ViconNexusLocal'. 'GraphView'. In the 'System' tab, 'Resources' window select 'Forceplates', 'Forceplate 1', 'force', 'Fz'.
3) Open the 'data management' window of Nexus and select 'tests', 'forceplate stability'.
4) Make a new session called FP(no of forceplate)-date eg. FP112-Feb-10.
5) Import the session to Nexus using the middle button in the 'resources' window, accept 'forceplate stability' as the patient name, and select 'GuysPlugInGait'
6) To begin data collection click 'start' in the data collection window.
7) The other member of staff puts weights of 10, 20, 40, 60, 80, 100kg onto forceplate one leaving a few seconds in between each addition.
8) After 100kg has been added to forceplate 1, press stop.
9) Save the trial as 'LaboratoryForcePlateRoutineStaticCalibration..plus the date' eg. LaboratoryForcePlateRoutineStaticCalibration25-oct-2010.
10) Repeat stages 6-9 on forceplate 2 and 3.
11) To process the results of the trials open the trial in NexusLocal. In the 'Resource' window go to 'Forceplates', 'Force', 'Fz' and select 'GraphView' in the middle window. Use the slider bar to view the forces recorded for each weight, and record this dat on the ForceplateStability' template.
12) Repeat stages 11 and 12 for forceplate 2 and 3.

11.28 Calibration of anthropometric measuring equipment

C6 Protocol for simple measurements tool check

Author: Tanya Sale and Adam Shortland 10/03/2010
Approved: Adam Shortland 10/03/2010

Perform the following checks annually:

Tape measure

The white and purple tape measure is routinely used for clinical examination measurements.
Check 3 15 cm sections of the measuring tape. These should be between 10 and 25 cm, 40 and 55 cm, and 80 and 95 cm as indicated on the tape. Use the Vernier callipers (the Gold standard) to define a 15 cm length. If any discrepancy is larger than 0.2 cm discard the tape measure, get a new one and repeat checks.

Stadiometer

Check 3 15 cm sections of the metal carpet measuring tape. These should be between 10 and 25 cm, 100 and 115 cm, and 150 and 165 cm as indicated on the tape. Use the Vernier callipers (the Gold standard) to define a 15 cm length. If any discrepancy is larger than 0.2 cm discard the tape measure, get a new one and repeat checks.

Large Calipers

Check 15 cm inter-calliper distance using Vernier calliper. If any discrepancy larger than 0.3 cm modify ratchet mechanism.

Small Calipers

Check 15 cm inter-calliper distance using Vernier calliper. If any discrepancy larger than 0.3 cm replace callipers.

Goniometer

Place goniometer over laminated template with the centre of the goniometer over the central dot. Place one arm of the goniometer on the reference line. Then place the moveable arm at each of the following indicated graduations (0, 30, 60, 90, 120, 150, 180 ,210, 240, 270, 300, 330 degrees). If any of the measurements disagree by any more than three degrees, replace goniometer and repeat.

Signed (HoD):.. Date:.................................

C3_Protocol for calibration of gait lab weighing scales

Author: Tanya Sale, Adam Shortland
Date: 12th February 2010
Last Reviewed: 05/03/10 (APS)
Modified: 28-oct-2010 (APS)
-to be performed at six monthly intervals.

1) Open 'GaitLabDocs', 'MedicalDeviceCalibrationChecksWeighingScalesStability', 'LabWeighingScalesRoutineCalibrationCheck'
2) Turn on the weighing scales.
3) Note the value the scales are reading with no weight applied in the excel spreadsheet 'LabWeighingScalesRoutineCalibrationCheck' as described in note (1).
4) Put a 10kg weight on the scales and note the value the scales are recording in the excel spreadsheet.
5) Repeat for weights of 20, 40, 60, 80 and 100kg and record in the excel spreadsheet.
6) Save the completed form as an excel 97-2003 workbook with the same name and the date on the end eg: LabWeighingScalesRoutineCalibrationCheck12-Feb-10.
7) Check the values are within the 5% accepted error

Signed (Hod):..
Date:...........................

11.29 Protocol for marker placement

Date: 10/10/08
Author: Adam Shortland/Tanya Sale
Modified: 05/03/10 (TS/APS)
Reviewed: 05/03/10 (APS)
Modified: 04-05-12 Tanya Forster. (SENIAM guidelines reference added)
Approved: 04-05-12 Adam Shortland

Scope: For placement of lower limb markers for routine clinical gait analysis in the One Small Step Gait Laboratory

With the patient sitting with legs off the side of the plinth place markers in the following order:

Ankle marker bilaterally: Mark most prominent point of lateral malleolus. Stick marker to the lateral malleolus with the centre of the circular base of the marker over the marked point.

Forefoot marker bilaterally: Mark position on dorsum of foot between 2nd and 3rd rays just proximal to the equinus break between forefoot and midfoot. Stick down marker with the centre of the circular base of the marker over the marked point.

Heel marker bilaterally: It should be placed on the back of the heel so that the line joining it to the forefoot markers reflects the long axis of the foot. If the subject is able to stand with foot flat height of the heel marker is unimportant provided foot flat check box in the trial form is set before processing. Mark point on hindfoot that is approximately at the same height from the sole of the foot as the forefoot marker. Stick down marker with the centre of the circular base of the marker over the marked point.

Shank marker bilaterally: placed on the lower third of the shank on a line between the estimated flexion axis of the knee and the lateral malleolus marker. Alignment of the shank marker is carried out at the end of marker placement.

Knee Marker Bilaterally: Place a marker halfway between the most prominent point of the lateral epicondyle and the knee joint line.

Thigh Marker Placement: Placed over the lower third of the lateral thigh.

ASIS: ASIS markers on left and right Palpate ASIS bilaterally and place marker directly over these points. If the patient is obese or the markers cannot be placed directly over the ASIS' bilaterally, move the markers laterally by equal distance and enter the ASIS distance measured in the static exam.

Sacrum Marker Bilaterally: Palpate posterior superior iliac spines bilaterally. Place a marker on the skin midway between both posterior superior iliac spines.

Place a marker on the ischial crest bilaterally

Marker Alignment:

Have patient stand sideways on to mirror. Align patient so that the knee axis is perpendicular to the plane of the mirror. By looking in the mirror place the thigh marker so that it is aligned with the greater trochanter and knee marker. Align the child so that the ankle axis is perpendicular to the mirror (this may involve turning the child slightly). Place the shank marker in line with the imagined position of the knee joint centre and ankle marker.

Signed.. Date:...

HoD

11.30 Error analysis to demonstrate robustness of determining heel strike and foot offs from a participant's kinematic compared to force plate data.

Introduction

To determine spatio-temporal parameters in the biomechanical studies it was necessary to define heel strike and foot off phases of gait within Vicon Nexus (movement analysis software supplied by Vicon Motion Systems, Oxford, UK). Using force plate data to identify these phases of the gait cycle is the method of choice. However, in trials without force plate data, or where force plate data were contaminated, gait cycle events were determined through observation of the patterns of the heel and forefoot trajectories. The latter method may have resulted in an imprecision in the labelling of gait cycle events, potentially resulting in an error in the spatio-temporal data obtained. In order to determine the size of the potential error, an error analysis was conducted.

Methods

Ten barefoot gait trials were selected (by Dr Adam Shortland [AS]) from participants' barefoot baseline assessment gait data (Chapter 7). These trials all had force plate data from which the events of foot strike and foot off could be marked. All heel strike and toe off event locators, inserted previously by Sian MacRae for analyses of trial data, were removed by AS. Duplicate copies of each trial were made, one copy enabling SM to visualise the force plate ground reaction vectors, whilst on the duplicate copy the option to visualise ground reaction vectors was removed. The twenty trials (10 with ground reaction vectors visible and 10 without) were randomly ordered by AS. SM then reviewed all trials, inserting heel strike and toe off phases of gait, for one gait cycle (a total of seven events), occurring across the three force plates. When force plate data was present, SM located gait events from observation of the ground reaction vectors. For trials absent of ground reaction vector data SM located heel strike and toe-off phases of gait through visual inspection of patterns of the heel and forefoot trajectories.

Following the labelling of all events, SM documented the frame number of each labelled heel strike and toe off event for each trial. SM was then unblinded to which trials were the matching pairs. SM inspected the frame numbers recorded for each event, and documented the number of frames differences between the paired data (with and without force plate data). AS developed a computer programme (developed in Visual Basic for Applications, Microsoft, Berkshire, UK) which randomly generated errors in the gait events of all trials analysed in the baseline barefoot assessment of the twenty CLBP participants assessed in Chapter 7, according to the documented distribution of errors from the blinded analysis. Means and standard deviations were obtained for each participant for the cadence, stride length and walking speed, and compared to the results for the baseline data presented in Chapter 7.

Results

Table 1 shows the distribution of errors (difference between paired duplicate trials from which visualisation of force plate data has been removed). There were no errors greater than two frames (1/60th of a second). There was a wider distribution of errors for toe-off than for heel strike.

Table 1. Percentage of gait events labelled through visual inspection of kinematic data that were identical and different to those labelled from observation of force plate data.

Phase of gait cycle	Difference in frame numbers identified as gait cycle events between trials with and without force plate data (%)				
	-2 frames	-1 frame	No difference	+1 frame	+2 frames
Toe-off	10	20	45	15	10
Heel strike	5	15	50	25	5

Table 2 demonstrates the mean data obtained in Chapter 7 for baseline barefoot gait, and the mean data and standard error of the mean obtained following the error analysis calculations. The simulated analysis incorporating the error distribution produced very similar results to the original analysis with 1 % error in estimated walking speed, stride length and cadence.

Table 2. Baseline barefoot mean spatio-temporal data obtained in Chapter 7 and following the error analysis calculations

	Walking speed (m/s)	Stride length (m)	Cadence (steps/min)
Chapter 7 mean (SD)	1.245 (0.200)	1.334 (0.130)	112.433 (11.805)
Error analysis mean (SD)	1.236 (0.196)	1.322 (0.136)	111.898 (11.247)

(SD: standard deviation; m: metres: s: seconds; min: minutes)

Discussion

This error analysis investigated the concern that differences in the marking of temporal events due the presence or absence of force plate data may have affected the results for the temporal parameters (walking speed, stride length, cadence) in the study. From the analysis it seems that there are no systematic deviations between events marked with the aid of force plates and those marked without (Table 1), and that the random error is so small (maximum of two frames) that its impact on the results from the biomechanical studies would be minimal (Table 2).

Limitations

The error analysis was performed on only barefoot gait. It is possible that the errors between force plate-assisted and non-assisted event labelling may be greater in shod trials.

Implications

The error analysis study suggests that the approach used to determine phases of gait in the biomechanical studies is a robust approach.

11.31 Biomechanical study ethical approval letter

Outer North London REC
Northwick Park Hospital
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Telephone: 020 8869 3020
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15 March 2010

Miss Sian MacRae
Doctoral Student
King's College London
School of Biomedical & Health Science
PhD Office, Room SH 3.11
Shepherd's House, Guy's Campus
SE1 1UL

Dear Miss MacRae

Study Title:	**Low back pain: Can shoe type reduce the pain and recurrence rate? A biomechanical assessment.**
REC reference number:	**10/H0724/7**
Protocol number:	**1**

Thank you for your letter of 09 March 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by me (Committee Chair).

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm **a favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

Sponsors are not required to notify the Committee of approvals from host organisations.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		01 February 2010
REC application	1	29 January 2010
Protocol	1	29 January 2010
Investigator CV		29 January 2010
Participant Consent Form	1	29 January 2010
GP/Consultant Information Sheets	1	29 January 2010
Evidence of insurance or indemnity		
Advertisement	1	28 November 2008
Supervisor's CV		29 January 2010
Roland Morris Disability Questionnaire		
Evidence of insurance or indemnity		
Participant Information Sheet	2	09 March 2010
Response to Request for Further Information	email	09 March 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H0724/7	**Please quote this number on all correspondence**

Yours sincerely

Mrs Rosemary Hill
Chair

Email: uzma.chaudhry@nwlh.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to:

Mr Keith Brennan
King's College London
1.8 Hodgkin Building
Guy's Campus
London
SE1 1UL

Ms Karen Ignation
Guy's and St. Thomas' NHS Foundation Trust
16th Floor, Guy's Tower Wing
Guy's Hospital
Great Maze Pond
SE1 9RT

11.32 Biomechanical study consent form

Guy's Hospital
St Thomas Street
London SE1 9RT
Tel: 020 7188 7188

Research Subject Consent Form

Title of Project: **Low back pain: Can shoe type reduce the pain and recurrence rate? A biomechanical assessment.**

Protocol Version: Version 1 Date 29.01.10

Local Research Ethics Number: 10/H0724/7 R & D Registration Number:

Patient Hospital Number: Patient Study Identification Number:

Patient Initials:

Participant Declaration

	Please initial box if correct
I have been given the chance to read and understand the information sheet (dated 29.01.10) relating to the above study	☐
I have been given the opportunity to ask questions and discuss the study.	☐
I have been made aware of the risks/ benefits	☐
I understand that authorised individuals may look at my medical notes and give permission for these individuals to have access	☐
I understand that I am free to withdraw from this study at any time without prejudice to my future care/ treatment	☐
I have had the compensation procedures explained to me	☐
I would like my GP or consultant to know that I am participating in this research project.	☐
I would like to receive a one page summary of the findings of this study.	☐

Title of Project: **Low back pain: Can shoe type reduce the pain and recurrence rate? A biomechanical assessment.**

Local Research Ethics Number: 10/H0724/7

R & D Registration Number:

Patient Hospital Number:

I agree to take part in the above study

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

Person responsible for obtaining Informed Consent:
'To the best of my knowledge I have provided the above individual with sufficient information to enable them to give informed consent'.

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

Position ……………………………………………………………

Witnessed by:

Signature ……………………………………………………………

Name ……………………………………………………………

Date ……………………………………………………………

11.33 King's College London Ethics approval for biomechanical study investigating asymptomatic individuals

13 June 2011

Dear Sian,

BDM/10/11-71 Biomechanical assessment of asymptomatic individuals whilst standing and walking

Thank you for sending in the amendments requested to the above project. I am pleased to inform you that these meet the requirements of the BDM RESC and therefore that full approval is now granted with the following proviso:

1. Section 5.3: Given that you intend to recruit friends and colleagues, it is strongly recommended that you consult the Research Ethics office guidelines, *Research in the Workplace*. These are accessible at the link below:

   http://www.kcl.ac.uk/research/ethics/training/workplace.html

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information ethical approval is granted until 13 June 2012. If you need approval beyond this point you will need to apply for an extension to approval at least two weeks prior to this explaining why the extension is needed, (please note however that a full re-application will not be necessary unless the protocol has changed). You should also note that if your approval is for one year, you will not be sent a reminder when it is due to lapse.

If you do not start the project within three months of this letter please contact the Research Ethics Office. Should you need to modify the project or request an extension to approval you will need approval for this and should follow the guidance relating to modifying approved applications: http://www.kcl.ac.uk/research/ethics/applicants/modifications.html

Any unforeseen ethical problems arising during the course of the project should be reported to the approving committee/panel. In the event of an untoward event or an adverse reaction a full report must be made to the Chairman of the approving committee/review panel within one week of the incident.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.
If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (http://www.kcl.ac.uk/research/ethics/contacts.html). We wish you every success with this work.

With best wishes

Yours sincerely

James Patterson – Senior Research Ethics Officer

Cc: Duncan Critchley

11.34 Asymptomatic study participant information sheet

INFORMATION SHEET FOR PARTICIPANTS

REC Reference Number: BDM/10/11-71

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Biomechanical assessment of asymptomatic individuals whilst standing and walking.

We would like to invite you to participate in this postgraduate research project. You should only participate if you want to; choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being conducted and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

Aims of the research and possible benefits.

In this study we are aiming to determine if there is a difference in how people with and without lower back pain stand and walk. We will assess this in a gait laboratory. We will compare the data from this study with data collected from a similar sample of people who have lower back pain. The data from people with lower back pain has been collected in a preceding research trial.

Who are we recruiting?

If you are aged between 18 and 65 years and have had no history of lower back pain in the past year you may be eligible to participate in this research study. However, if any of the following points are true for you, you will not be able to participate: known structural spinal deformity; previous spinal surgery; fracture of the spine within the past year; inflammatory disease of the spine; spinal infection; severe cardiovascular or metabolic disease; pregnancy; known Mortons Neuroma; skin ulcerations over the foot; peripheral neuropathy with loss of sensation; history of falls; surgery to the lower limb less than 8 weeks ago; recent deep vein thrombosis yet to be stabilised by anti-coagulation therapy; those who have previously used rocker-bottom shoes e.g. MBT's or FitFlops.

What will happen to me if I take part?

The aims of the biomechanical study are to assess your posture, balance and the way you move. If you chose to participate in this study you will be required to attend the One Small Step Gait Laboratory at Guy's hospital on one occasion. You will be asked to wear shorts and a T-shirt/vest top for the assessment.

The assessment in the gait laboratory will consist of the following:

- You will also be asked to complete a consent form and questionnaire relating to your day to day activities. This should take 2-3 minutes to complete.
- You will be asked to bring with you a pair of shorts and a t-shirt or vest top to change into for the assessment. We will also ask you to remove your shoes and socks. Measurements of your

lower limbs will be recorded by the co-researcher (Dr Adam Shortland) during your visit using a tape measure or callipers. These will include the width of your ankles, knees and pelvis, and the length of your legs. These measurements will be used by the primary investigator (Sian MacRae) in the analysis of the data recorded during your visit. We will also record your height and weight.

- Small reflective markers (21 in total) will be placed at different points on your legs, on your lower abdomen, and on your lower back region, which will enable us to analyse how you are moving during the tasks. The markers will be placed on your legs, pelvis and trunk with double sided sticky tape, and removed at the end of the assessment.
- You will be asked to stand with each leg on a separate force plate (a force plate is a measuring instrument on the floor, with the appearance of a normal floor tile, that measures forces generated by you whilst standing on or moving across it) for three 40 second trials under the following balance situations:
    - Standing barefoot with your eyes open
    - Standing barefoot with your eyes closed
    - Standing with each foot on a separate foam cushion with your eyes open
    - Standing with each foot on a separate foam cushion with your eyes closed

For the eyes-closed assessments we will ask you to wear a blindfold.

You will also be asked to walk in the laboratory, whilst still wearing the markers. We will ask you to walk for approximately 10 meters and repeat this approximately 5 times. This will enable us to assess the movements that occur at your joints, and the forces that occur whilst you are walking barefoot.

The assessment in the laboratory will take approximately 1 hour. Please remember that you are free not to participate and you are free to leave the study for whatever reason you choose at any stage.

What are the side effects of taking part?

Following the removal of the body markers at the end of the biomechanical assessment you may be aware of a slight redness/itchiness of the area directly underlying where the marker had been placed. This is normal and should settle in approximately one hour.

What are the possible advantages of taking part?

We hope to use the information we obtain from this study to inform other health professionals about our results by means of journal publications and conference presentations. The results will probably be published about one year after the end of the study and if you are interested in finding out about our results, we would be happy to send you a one page summary of our findings.

What are the possible disadvantages and risks of taking part?

There are no perceived disadvantages or risks for those taking part in this study. The examination procedures are ones used daily in gait laboratories.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the gait laboratory will have your name removed so that you cannot be recognised from it.

Who is organising and funding the research?

This research is being organised by the Division of Health and Social Care, Kings College London.

It is up to you to decide whether to take part or not. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part and then decide at any time during the research that you no longer wish to participate in this project, you can notify the researchers involved and withdraw from it immediately without giving any reason. If you have any general queries regarding the study you may contact the Primary Investigator using the details below for further advice and information:

Primary Investigator: Sian MacRae
Email: sian.macrae@kcl.ac.uk
Division of Health and Social Care
School of Medicine
King's College London
Shepherd's House 3.11
Guy's Campus
London SE1 1UL
Tel: 020 7848 6679

If this study has harmed you in any way you can contact King's College London using the details below for further advice and information:

Dr Duncan Critchley (PhD Primary Supervisor)
Email: duncan.critchley@kcl.ac.uk
Academic Department of Physiotherapy / Division of Health and Social Care
School of Medicine
King's College London
Shepherd's House 3.18
Guy's Campus
London SE1 1UL
Tel: 020 7848 6678

11.35 Asymptomatic study consent form

CONSENT FORM FOR PARTICIPANTS IN RESEARCH STUDIES

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Title of Study: Biomechanical assessment of asymptomatic individuals whilst standing and walking.

King's College Research Ethics Committee Ref: BDM/10/11-71
Thank you for considering taking part in this research. The person organising the research must explain the project to you before you agree to take part. If you have any questions arising from the Information Sheet or explanation already given to you, please ask the researcher before you decide whether to join in. You will be given a copy of this Consent Form to keep and refer to at any time.

	Please tick or initial
I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data up to the point of publication.	☐
I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be handled in accordance with the terms of the Data Protection Act 1998.	☐
I understand that I must not take part if I have: known structural spinal deformity; previous spinal surgery; fracture of the spine within the past year; inflammatory disease of the spine; spinal infection ; severe cardiovascular or metabolic disease; pregnancy; known Mortons Neuroma; skin ulcerations over the foot; peripheral neuropathy with loss of sensation; history of falls; surgery to the lower limb less than 8 weeks ago; recent deep vein thrombosis yet to be stabilised by anti-coagulation therapy; previously used rocker-bottom shoes e.g. MBT's or FitFlops.	☐

Participant's Statement:

I ____

agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed **Date**

Investigator's Statement:
I ____

Confirm that I have carefully explained the nature, demands and any foreseeable risks (where applicable) of the proposed research to the participant.

Signed **Date**

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